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Contracting Official Name Kathleen	Rechenberg				nch/Mail Code:		
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## PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-16-011 WORK ASSIGNMENT #3-12

**Title:** Preliminary Economic Analysis and Modeling Support: Per-and Polyfluoroalkyl Substances (PFAS)

## Work Assignment Contracting Officer Representative (WACOR):

Austin Heinrich

U.S. Environmental Protection Agency (U.S. EPA)

Office of Water, Office of Ground Water and Drinking Water Standards and Risk Management Division (Mail Code: 4607M)

Heinrich.austin@epa.gov Phone: 202-564-6723

#### Alternate Work Assignment Contracting Officer Representative (Alt WACOR):

Hannah Holsinger

U.S. Environmental Protection Agency (U.S. EPA)
Office of Water, Office of Ground Water and Drinking Water

Standards and Risk Management Division (Mail Code: 4607M)

Holsinger.hannah@epa.gov

Phone: 202-564-0403

**Contract PWS: Section 3.1** 

**Estimated Level of Effort:** 1,635 Hours

**Period of Performance:** July 1, 2019 through June 30, 2020

#### **Background and Purpose:**

Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that includes PFOA, PFOS, GenX chemicals, and many other chemicals. PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s. PFOA and PFOS have been the most extensively produced and studied of these chemicals. Both chemicals are very persistent in the environment and in the human body – meaning they do not break down and they can accumulate over time. There is evidence that exposure to PFAS at certain levels can lead to adverse human health effects. In 2016, U.S. EPA established non-enforceable health advisories for PFOA and PFOS based on assessment of peer-reviewed science to provide Americans (including sensitive subpopulations) with a margin of protection from a lifetime of exposure to PFOA and PFOS in drinking water (see <a href="https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos">https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos</a>).

EPA is considering different PFAS risk-mitigation approaches, including the development of guidance and regulatory actions. As part of any potential future rulemaking process, the Safe Drinking Water Act requires U.S. EPA to prepare a health risk reduction and cost analysis (see

https://www.epa.gov/dwregdev/economic-analysis-and-statutory-requirements). In these assessments, quantitative and qualitative benefits of a proposed rule are measured against its cost.

Under this work assignment (and building off the work conducted under previous WA 2-12), the contractor shall develop a preliminary economic analysis, and as appropriate, other related preliminary rule analyses to be used to inform U.S. EPA about potential effects of selected regulatory scenarios. This analysis would be used as the foundation for any future health risk reduction and cost analysis should U.S. EPA ultimately evaluate whether to initiate rulemaking for any PFAS: any such framework should be mindful of statutory obligations found in 300g-1(b)(3)(c) of the Safe Drinking Water Act (SDWA), including "quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the maximum contaminant level" (See 300g-1(b)(3)(c)(II)). The contractor shall complete the analysis in multiple steps, as explained in the work assignment tasks herein. A summary report comparing the potential effects of multiple PFAS regulatory scenarios will be one of the final products delivered under the work assignment. Additionally, the contractor shall deliver all supporting files and related information prior to the conclusion of the option period. The contractor shall consider, with input from the WACOR, U.S. EPA's guidelines for preparing economic analyses (see https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses) throughout the development of all products produced under this work assignment.

#### General Requirements of the Performance Work Statement and Schedule:

Confidential Business Information (CBI): During the course of the work assignment, the contractor shall be accessing and evaluating CBI. As such, the contractor shall adhere to U.S. EPA's CBI policy and procedures as described in the Section H contract clauses. The contractor must maintain CBI security clearance to use CBI information. The contractor shall not disclose any CBI to anyone other than applicable U.S. EPA personnel without prior written approval from the WACOR. The contractor shall, at all times, adhere to Confidential Business Information (CBI) procedures when handling industry information. The contractor shall manage all reports, documents, and other materials and all draft documents developed under this work assignment in accordance with the procedures set forth in the Section H contract clauses.

Budget Reporting: The contractor, under this work assignment, is required to report to the WACOR when 80 percent of the total work assignment funding amount has been depleted. The contractor must also report to the WACOR when 80 percent of the approved Workplan budget has been depleted. The contractor must report, at a monthly minimum, the hours of labor and dollars expended under this Performance Work Statement. The labor hours and dollars must be broken down by task.

<u>Identification as Contracting Staff:</u> To avoid the perception that contractor personnel are U.S. EPA employees, contractor personnel shall be clearly identified as independent contractors of U.S. EPA when participating in events with outside parties and prior to the start of any meeting.

The contractor personnel are prohibited from acting as the Agency's official representative. When speaking with the public, the contractor shall refer all interpretations of policy to the WACOR.

<u>Limitation of Contractor Activities:</u> The contractor shall submit drafts of all deliverables to the WACOR for review prior to submission of the final product. These drafts will clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources and data that support any conclusions and recommendations. The contractor shall incorporate all WACOR comments into all final deliverables, unless otherwise agreed upon by the WACOR. The contractor shall adhere to all applicable U.S. EPA management control procedures as implemented by the Contracting Officer (CO), Contract-Level COR (CL-COR), and the WACOR.

<u>Quick Response</u>: Under this work assignment, the contractor may be required to provide information for use by U.S. EPA for quick responses and analyses of options, issues, and policy decisions. Quick responses are those which require completion in one to five working days.

Deliverable Formatting: The contractor shall develop and deliver all documents and/or deliverables in Microsoft Office and/or Adobe Acrobat compatible PDF format unless noted otherwise. All draft versions shall be labeled as "internal deliberative, do not cite, quote or distribute." For deliverable documents that are intended to be shared with management or the public (as specified by the WACOR through written technical direction), the contractor shall provide the document in a Section 508 format in accordance with the policies referenced at <a href="http://www.epa.gov/accessibility/">http://www.epa.gov/accessibility/</a>. All final materials, e.g., memos, chapters, etc. are to be prepared only after receiving written technical direction from the WACOR. Deliverable deadlines shall be provided in technical direction, after evaluating time needed for efforts in consultation with the contractor. All products shall be original work or use appropriate citation cite to original sources.

#### Tasks:

The WACOR will review all deliverables in draft form and provide revisions and/or comments to the contractor. The contractor shall prepare the final deliverables incorporating the WACOR's comments.

#### Task 1 - Prepare Workplan and Monthly Progress Reports

The contractor shall prepare a workplan within 20 calendar days after receipt of performance work statement. The workplan shall outline, describe, and include the technical approach, resources, timeline and due dates for deliverables, a detailed cost estimate by task, and a staffing plan. The workplan shall include the requirement that all electronic and information technology (EIT) and all EIT deliverables be Section 508 compliant in accordance with the policies referenced at <a href="http://www.epa.gov/accessibility/">http://www.epa.gov/accessibility/</a>.

The WACOR will review the workplan, however, only the CO can approve/disapprove, the workplan. Official revisions will be given to the contractor by the Contracting Officer. The

contractor shall prepare a revised workplan incorporating the Contracting Officer's comments, if required.

A weekly update call with the WACOR will be required for this work assignment to discuss progress on deliverables, costs, and other potential issues. This task also includes written monthly progress and financial reports. The Monthly Progress Report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly reports must include a table with the invoice LOE and costs broken out by the tasks in this PWS.

#### Deliverables:

- Workplan is due within 20 calendar days after receipt of work assignment
- Monthly progress reports per contract requirements

For the purposes of the cost estimate, the WACOR estimates that task 1 will require approximately 5% of the total technical LOE.

#### Task 2 – Quality Assurance

U.S. EPA policy requires that an approved Quality Assurance Project Plan be in place before commencing any work that involves the collection, generation, evaluation, analysis or use of environmental data. Tasks 3 through 6 in this work assignment require the use of primary and/or secondary data. Under task 2, the contractor shall track quality assurance processes consistent with the Supplemental Quality Assurance Project Plan (SQAPP) developed under WA 2-12 and the Contract Level Quality Assurance Project Plan (QAPP). The project-specific QA requirements must be detailed in the monthly progress reports as specified under task 1, above.

The contractor shall immediately notify the WACOR if any changes to the tasks involving the collection and analysis of the data occur and prepare a new SQAPP supplementing the Contract Level QAPP accordingly. Work on these tasks cannot proceed until the contractor receives notification of the new SQAPP approval from the WACOR and QA official via e-mail.

#### Deliverables:

OA tracking required in monthly progress reports in accordance with task 1

For the purposes of the cost estimate, the WACOR estimates that task 2 will require approximately 5% of the total technical LOE.

#### Task 3 - Scoping

The contractor shall review information related to PFAS health effects and occurrence for the purposes of using this information for economic analysis. Additionally, the contractor shall review economic data (e.g., on morbidity and mortality costs). This information will be used and described in the summary report, which will be developed under task 6. This task will involve the review of information used to develop the U.S. EPA drinking water health advisories for PFOA and PFOS, as well as the collection and review of additional sources that have become available since the development of the health advisories. Literature sources shall be explored by

considering their possible usefulness in an economic analysis.

Types of support may encompass the following areas per WACOR direction:

- Evaluation of potential health effects (and weight of evidence of those effects) through review of both epidemiological and toxicological information
- Identification of possible data sources on PFAS occurrence that could be used to inform economic (and sensitivity) analysis
- Use of systematic review tools to search and categorize literature
- Review of economic data to identify health outcomes (from oral ingestion of drinking water containing PFAS) that can be monetized
- Selection of health outcomes (based on weight of evidence and other factors) for consideration in benefits monetization
- Development of summaries for the most important literature and data sources
- Identification of data gaps and limitations

The specific scope of review and analyses related to this information will be provided through written technical direction from the WACOR. Deliverables shall be sent in Microsoft Word, Excel, Access and/or PowerPoint format as directed by the WACOR. Final documents and reports shall be delivered in both Microsoft Word and PDF (508-compliant for materials to be released publicly) formats.

#### Deliverables:

- Excel files documenting literature collected and reviewed
- Draft documents and reports

For the purposes of the cost estimate, the WACOR estimates that task 3 will require approximately 15% of the total technical LOE.

#### Task 4 – Baseline

The baseline of an economic analysis is a reference point that reflects the world without the proposed regulation. It is the starting point for conducting an economic analysis of the potential effects of a proposed regulation. Under this task (and after consulting with Agency PFAS occurrence experts), the contractor shall characterize the current conditions with respect to the occurrence of PFOA, PFOS, and other relevant PFAS as the starting point for understanding the impact that potential regulatory development may have. This information will be used and described in the summary economic analysis report, which will be developed under task 6.

Types of support may encompass several areas per WACOR direction, including:

- Analysis of National Contaminant Occurrence Database (NCOD) data, specifically PFOA/PFOS monitoring information collected under U.S. EPA's UCMR3 program
- Evaluation of other data sources identified under task 3
- Spatial/temporal PFAS characterizations and consideration of effects in environmental justice groups and sensitive subpopulations
- Development of summaries detailing analyses
- Identification of data gaps, uncertainty, limitations, and assumptions

The specific scope of review and analyses related to this information will be provided through written technical directions from the WACOR. Deliverables shall be sent in Microsoft Word, Excel, Access and/or PowerPoint format as directed by the WACOR. Final documents and reports shall be delivered in both Microsoft Word and PDF (508-compliant for materials to be released publicly) formats.

#### Deliverables:

- Draft analytical results
- Final analytical results
- Draft documents and reports

For the purposes of the cost estimate, the WACOR estimates that task 4 will require approximately 15% of the total technical LOE.

#### Task 5 – Risk, Benefit and Cost Estimation

This task is comprised of two parts: 1. Risk estimation for key health effects (identified under task 3), and 2. The estimation of benefits and costs resulting from potential PFAS regulatory scenarios. This information will be used and described in the summary economic analysis report, which will be developed under task 6.

#### Part 1.

Based on the studies identified under task 3, the contractor may be asked to develop concentration-response functions or other metrics of health impacts (collectively referred to here as "risk estimate") for each selected health effect. The process to develop risk estimates using the identified study data could proceed in different ways depending on the available data, the quality of the data in each study, and the health effect. The contractor shall consider dose-response and other toxicological and epidemiological information through consultation with the WACOR and U.S. EPA subject matter experts, when appropriate.

Types of support under part 1 of this task may encompass the following areas per WACOR direction:

- Quantifying odds ratios and/or population attributable risk associated with various levels of PFAS in drinking water
- Developing a point of departure associated with a given health effect, such as noobserved effect levels or benchmark doses
- Combining raw data from multiple sources to develop a meta-analysis measure of hazards
- Using a physiologically based pharmacokinetic (PBPK) model to translate PFAS drinking water concentrations leading to an effect in animals to the water concentration leading to the same effect (as measured by the serum or urine concentrations) in humans
- Development of summaries
- Identification of data gaps, uncertainty, limitations and assumptions

#### Part 2.

The contractor shall monetize estimated benefits from potential reductions in PFAS drinking water exposure. This process may involve estimating the baseline incidence of the selected health effects in the US population, as well as prevalence in sensitive subpopulations. These measures may provide a baseline prevalence of these effects in the US populations, which will be the basis for comparing the estimated incremental incidences of cancer and other diseases associated with exposure to PFAS.

To the extent feasible, the contractor shall monetize benefits from reductions in both morbidity and mortality, for those health endpoints with sufficient information to do so. The contractor shall rely on U.S. EPA's estimate of the value of statistical life saved (VSL) for all mortality endpoints. To value morbidity effects the contractor shall rely on available cost of illness (COI) estimates (or ranges of COI estimates based on similar endpoints). The contractor will not be tasked to develop COI estimates; however, the contractor shall use COI estimates from peer-reviewed sources.

Through written technical direction from the WACOR, the contractor may also consider treatment, operation and/or monitoring cost information for the purposes of developing a benefit-cost ratio.

Types of support under part 2 of this task may encompass the following areas per WACOR direction:

- (Cases of) illness estimates for various levels of PFAS exposure based on risk estimates from part 1
- Estimated, monetized health benefits from different PFAS regulatory scenarios designed to limit exposure presented at different discount rates (e.g., 3 and 7%)
- Estimated rule costs, presented at different discount rates (e.g., 3 and 7%)
- Evaluation of data sources (e.g., from the Centers for Disease Control and Prevention, National Institute of Health) to determine baseline disease incidence in US population

The specific scope of review and analyses related to this information will be provided through written technical directions from the WACOR. Deliverables shall be sent in Microsoft Word, Excel, Access and/or PowerPoint format as directed by the WACOR. Final documents and reports shall be delivered in both Microsoft Word and PDF (508-compliant for materials to be released publicly) formats, as directed by the WACOR.

#### Deliverables:

- Draft analytical results
- Final analytical results
- Draft documents and reports

For the purposes of the cost estimate, the WACOR estimates that task 5 will require approximately 30% of the total technical LOE.

#### Task 6 – Summary Report (economic analysis and additional support documents)

This report will effectively present background PFAS information and problem statements, key data sources, and baseline PFAS conditions. Additionally, the report will present the PFAS health effects considered for benefits estimates, different regulatory scenarios intended to prevent those effects, and finally the estimated benefits from reductions in PFAS drinking water exposure. The report shall also highlight other potential benefits that could be considered for future analyses, but which were not quantified for this report because of time and resource limitations. The contractor shall develop a qualitative discussion on benefits for those endpoints where sufficient information is lacking. The contractor may also evaluate and present auxiliary benefits that could arise from reductions in other drinking water contaminants because of PFAS treatment in water systems.

Additionally, the contractor shall, as directed by the WACOR through technical direction, provide additional support by updating and/or developing support documents as needed and providing other general support as needed. This support may include but not be limited to developing draft responses for comment response documents focusing on occurrence and health information, developing information to support regulatory determination options such as potential PFAS groupings, and developing materials to support risk communication of PFAS.

Types of support may encompass the following areas per WACOR direction:

- Production of a final report, showing analysis process and an overall assessment of economic effects
- Development and presentation of different regulatory scenarios
- Presentation of data gaps, uncertainty, limitations and assumptions

The specific scope of review and analyses related to this information will be provided through written technical directions from the WACOR. Deliverables shall be sent in Microsoft Word, Excel, Access and/or PowerPoint format as directed by the WACOR. Final documents and reports shall be delivered in both Microsoft Word and PDF (508-compliant for materials to be released publicly) formats.

#### Deliverables:

- Draft documents and reports
- Final documents and reports

For the purposes of the cost estimate, the WACOR estimates that task 6 will require approximately 30% of the total technical LOE.

## Milestones and deliverables<sup>1</sup>

Milestone	<b>Due Date</b>
Task 1: Work plan, monthly progress reports and quality assurance	
Workplan	Within 20 calendar days after receipt of work assignment
Task 2: Quality Assurance	
QA tracking required in monthly progress reports, see Task 1 for due date	On a monthly basis in accordance with task I
Task 3: Scoping	
Compiled excel files	By September 1, 2019
Draft documents and reports	By September 1, 2019
Task 4: Baseline	
Draft analytical results	By October 1, 2019
Final analytical results	By June 1, 2020
Draft documents and reports	By October 1, 2019
Task 5 – Risk, Benefit and Cost Estimation	
Draft analytical results	By September 1, 2019
Final analytical results	By June 1, 2020
Draft documents and reports	By October 1, 2019
Task 6 – Summary Report (Economic Analysis)	
Draft documents and reports	By November 1, 2019
Final documents and reports	By June 1, 2020

<sup>&</sup>lt;sup>1</sup> Schedules may be modified if mutually agreed to by the WACOR and contractor.

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### PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-16-011 WORK ASSIGNMENT #3-14

**TITLE:** Support for OPPT's Chemical Prioritization

#### WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

Clifton Townsend (MC-7403M) US EPA OCSPP/OPPT/RAD/AB1 1200 Pennsylvania Avenue, NW Washington, D.C. 20460

Phone: (202) 564-1576 Fax: (202) 564-3760

E-mail: townsend.clifton@epa.gov

#### ALTERNATE WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

Iris Camacho (MC-7403M) US EPA OCSPP/OPPT/RAD/AB1 1200 Pennsylvania Avenue, NW Washington, D.C. 20460

Phone: (202) 564-1229 Fax: (202) 564-3760

E-mail: Camacho.iris@epa.gov

Contract PWS: 2.0, 3.0, 3.1 3.3, 3.4, 3.5, 3.8 and 4.0

**LOE:** 3,900 hours

PERIOD OF PERFORMANCE: July 1, 2019 through June 30, 2020

#### **BACKGROUND:**

The Office of Pollution Prevention and Toxics (OPPT) of the U.S. Environmental Protection Agency (EPA) is responsible for work under a number of statutes including, principally, the Toxic Substances Control Act (TSCA), the Frank R. Lautenberg Chemicals Safety for the 21st Century Act, and Pollution Prevention Act of 1990 (PPA). The mission of the office is to assure that industrial chemicals are designed, manufactured, processed, and used in ways that maximize their benefits to society and minimize their impacts on human health and the environment; encourage the replacement of older, more hazardous chemicals and technologies with new, safer alternatives; and work to harness the use of pollution prevention technologies, whenever feasible.

OPPT's Risk Assessment Division (RAD) is responsible for health and environmental hazard and risk evaluations of chemicals regulated under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemicals Safety for the 21st Century Act amends the Toxic Substance Control Act (TSCA). Among other things, the amended TSCA requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation under the conditions of use. Most of the technical work occurs in OPPT/RAD but other divisions in OPPT may also engage in technical activities to support TSCA implementation activities.

Furthermore, the new TSCA legislation requires that EPA adhere to specific provisions regarding Scientific Standards, Weight of Evidence, and Availability of Information as articulated in Sections 26 (h), (i) and (j), respectively. TSCA requires that for each risk evaluation completed on a High-Priority Substance, EPA must begin a new risk evaluation. By the end of calendar year 2019, EPA must have at least 20 chemical risk evaluations ongoing at any given time on High-Priority Substances. EPA is currently in the process of completing the risk evaluations for the first 10 chemicals to meet the obligations under Lautenberg Chemical Safety Act. By December 22, 2019, EPA must have designated at least 20 chemical substances as High-Priority and 20 chemical substances as Low-Priority. Following the risk evaluations of the first 10 chemicals, EPA will conduct risk evaluations on chemical substances designated as High-Priority Substances through the Prioritization process.

The Agency is in the process of prioritizing the next 20 chemicals substances that must undergo regulation via the Lautenberg Chemical Safety Act.

The purpose of this work assignment (WA) is to provide technical support for technical products required to meet the obligations under the Lautenberg Chemical Safety for the 21st Century Act. Specifically, the WA will focus on TSCA prioritization work that includes the identification, compilation, characterization, analysis, synthesis, and prioritization of data sources reporting data/information on potential exposure and hazards for chemical substances. The work performed under this WA will primarily support the identification of chemical substances to be designated as High priority for potential risk evaluations. The initial list of substances will be selected from the updated 2014 TSCA Work Plan (referred as the 2014 Work Plan list; Appendix A) after excluding those chemical substances that have been initiated through ongoing TSCA implementation activities<sup>1</sup>. The chemicals on the 2014 Work Plan list will be subject to the prioritization process for determination of high- or low priority for risk evaluation.

This work assignment will cover ONLY tasks 1 through 3 for 5 chemicals to be evaluated. However, these tasks will also include support activities (e.g., literature searches) for risk evaluations for additional chemicals if deemed to be necessary by WACOR. The WACOR may also provide written technical direction (TD), as necessary, for additional work beyond these 5 chemicals substances, including support for overarching scientific issues (e.g., method development) that are important for the regulation of both new and existing chemicals under TSCA.

#### **QUALITY ASSURANCE:**

Tasks 1,3, and 4 in this work assignment may require the use of **secondary** data. Collection, use and analysis of data will be identical to the procedures described in the Programmatic Quality Assurance Project Plan (PQAPP) completed and approved. EPA has determined that this approved PQAPP is

<sup>&</sup>lt;sup>1</sup> Chemical substances that have been initiated through ongoing TSCA implementation activities are as follows: Asbestos, 1-Bromopropane, Carbon Tetrachloride, 1, 4 Dioxane, Cyclic Aliphatic Bromide Cluster (HBCD), Methylene Chloride, N-Methylpyrrolidone, Perchloroethylene, Pigment Violet 29 and Trichloroethylene. Decabromodiphenyl ethers (DecaBDE), Hexachlorobutadiene (HCBD), Pentachlorothiophenol (PCTP), Phenol, isopropylated, phosphate (3:1) and 2,4,6-Tris(tert-butyl) phenol are PBTs that were identified for action by EPA.

appropriate for the tasks outlined in this Performance Work Statement. Based on this determination, the contractor is not required to modify the approved PQAPP for this work assignment.

#### TASK DESCRIPTION:

#### Task 0: Work Plan and Monthly Progress Reports

The contractor shall develop a work plan that describes how each task will be carried out. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. In addition, the workplan shall include the requirement that all electronic and information technology (EIT) and all EIT deliverables be Section 508 compliant in accordance with the policies referenced at <a href="http://www.epa.gov/accessibility/">http://www.epa.gov/accessibility/</a>. If a subcontractor(s) is proposed and subcontractors are outside the local metropolitan area, the contractor shall include information on plans to manage work and control costs.

The workplan shall explain that collection, use and analysis of data in this work assignment. It should be identical to the procedures described in the PQAPP. This task also includes monthly progress and financial reports. The monthly progress report shall summarize activities conducted for the reporting period, and in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs` broken out by the tasks in this WA. The contractor shall immediately notify the WACOR if any changes to the tasks involving the collection and analysis of the data occur and prepare a SQAPP supplementing the Contract Level (QAPP] accordingly. Work on these tasks cannot proceed until the contractor receives the WACOR's notification of approval.

<u>Deliverables</u>: Work plan and monthly progress and financial reports submitted in accordance with contract requirements.

#### Task 1: Literature Search and Title/Abstract Screening

Under the ICF contract EP-C-14-001 WA 3-103 and 4-103, the contractor started the process to search for relevant information to assess and address the potential hazards, exposure and risks to workers, the general population, consumers and susceptible populations, for the first 10 chemicals undergoing TSCA risk evaluation. This also included searching for environmental fate information and characteristics of susceptible populations which might include age, sex, smoking status, pre-existing disease, genetic polymorphisms, socioeconomic status, race and ethnicity, body mass index, alcohol consumption, nutritional factors, and co-exposure to other chemical stressors. The contractor shall continue this task for the list of chemicals undergoing prioritization based on the 2014 Work Plan list. Although not anticipated, the WACOR may also ask the contractor to run literature searches to inform ecological risks.

#### Planning with EPA's Technical Team for Additional Chemicals:

- 1. Identify authoritative and/or trusted sources as well as secondary review articles in the peer-reviewed literature for each discipline searched (including environmental fate, engineering, exposure, human health) to help inform the type of data to be searched. In particular, this step will inform the process of preparing protocols, including preparing eligibility criteria in the form of Population, Exposure, Comparator and Outcome (PECO) or other relevant statements.
- 2. Prepare PECO and other statements (there will be slight differences by discipline) that identifies inclusion criteria and that will guide the literature search, title and abstract screening and subsequent full text screening (see task 2).

- 3. Work with WACOR and tech teams to develop exclusion criteria and design a tagging structure to organize the information. Use the tagging structures developed for the first 10 chemicals as a starting point.
- 4. Design search strategies for peer-reviewed and gray literature (e.g., government reports, industry websites) (as specified in the QAPP).
  - The contractor shall design searches that are comprehensive and as accurate as
    possible (that is, with as few "off-topic" studies as possible). This will include searching
    appropriate databases, using the most appropriate search terms as well as backwards
    reference searching. Forwards reference searching may also need to be used.
  - o In developing the search strategies, the contractor shall consider how to obtain:
    - Information that can be used to assess and address the risks to workers, the general population, consumers and susceptible populations, and from exposure during particular periods of development (i.e., life stages). Characteristics of susceptible populations might include age, location, sex, smoking status, pre-existing disease, pregnancy, genetic polymorphisms, socioeconomic status, race and ethnicity, body mass index, alcohol consumption, nutritional factors, and co-exposure to other chemical stressors.
    - Information on environmental fate information. The contractor might also be asked to obtain data on physical and chemical properties although this will primarily be gathered by EPA.
- 5. Document the search strategy, including the sources, search terms and logic, and tag structure in a protocol for each chemical and discipline (i.e., there will be one protocol per chemical per discipline).

#### **Execution**:

- 1. Pending OPPT approval of the protocol, conduct the literature searches and revise as needed (e.g., check whether a sample of previously identified on-topic studies were captured in the searches).
- 2. The contractor may assist the WACOR in conducting a pilot of applying the tags to the literature based on the tagging tree. If necessary, the pilot tagging will be conducted by two literature screeners per discipline (this may include one screener from ICF and one from EPA, but this will be specified in TD from the WACOR). These two screeners will review and tag the same 25-50 references. EPA will resolve any discrepancies in tagging.

o The tagging will be done using DistillerSR unless specified otherwise by Technical Direction (TD). All final tags will be uploaded in the Health and Environmental Research Online (HERO) where they can be accessed by both OPPT and the public.

3. Revise the protocol as necessary based on the pilot tagging and document changes in the protocol.

- 4. Implement full tagging with two literature screeners; EPA screeners may also be involved in this screening step.
- 5. Upload the final tagged results into HERO.

#### Assessment:

- 1. Check that the search results reflect a comprehensive search. This could be done, for instance, by doing backwards reference searching using authoritative or trusted literature sources, or by using additional experts. The contractor should identify additional ways to do this assessment.
- 2. ICF discipline lead reviews that the tags were applied accurately to a sample of references for each discipline.
- 3. Check that the results were uploaded correctly into HERO.

#### **Assumptions for Costing Purposes:**

For costing purposes, the contractor shall make the following assumptions:

Planning with EPA's Technical Team:

- Each ICF discipline lead, deputy, and researcher/note taker (see staffing plan) shall meet with their respective EPA(OPPT)technical team for up to six hours of total meeting time while executing this task.
- There shall be two rounds of review before each discipline's chemical protocols shall be considered ready for execution

#### Execution:

- The contractor shall assume that on average 7,500 references shall be tagged for each chemical
  across all disciplines and that tagging could take 1 minute per reference per screener (assume
  50 references will be tagged by two literature screeners during the pilot and 7,450 references
  will be tagged by only one literature screener).
- There shall be one round of updating each discipline's Protocol following the pilot tagging before it shall be considered final.
- Assume that 3,000 references per chemical shall be on-topic and the pdfs uploaded to HERO with each reference taking 5 minutes to upload.

#### Assessment:

EPA anticipates 20 hours of QA per chemical performed by each ICF discipline lead during the
literature search and tagging to ensure that the searches are as comprehensive as possible,
and tags are applied accurately.

If the actual time to review the references differs substantially from this estimate, or if the total number of studies to be tagged is higher or lower, the contractor shall contact the WACOR to determine the appropriate next steps.

When performing the literature searches, the contractor shall communicate with the WACOR and technical contacts regularly to ensure that searches are refined and focused.

The WACOR (through the Federal HERO Staff) will provide HERO access to expert authors and relevant personnel, both Federal and state.

If needed, revisions to this literature search strategy may be made based on TD from the WACOR. Although not anticipated, the WACOR may also ask the contractor to run literature searches to inform ecological risks.

#### **Deliverable Schedule:**

• All studies for newly identified chemicals imported into HERO from the Literature Search, and the empty Tag Tree set up on each Project Page: to be specified by written TD from the WACOR.

The contractor shall document the literature strategy and screening/sorting protocol in a document that will be provided to the WACOR as a deliverable. This document should include, as a minimum, the following information:

- keywords used and databases searched,
- number of references found in each database (PubMed, etc.)
- Tag Tree to be used for screening/sorting the references in each project (chemical).
- Literature search and screening protocol: to be specified by written TD from the WACOR.

#### Task 2: Screen Literature for Relevance via a Full-Text Screen

As directed by the WACOR in written technical direction, the contractor shall conduct full-text screening of the on-topic literature identified in Task 1 to identify data/information that are potentially relevant for the assessment questions needed to meet the analysis plan needs. The contractor shall update the PECOs and other statements in conjunction with EPA and then develop exclusion criteria to filter out studies that are not relevant for the assessment. The contractor shall document the exclusion criteria for each question in the Protocol for each chemical and discipline.

Pending the WACOR approval of the Protocol, the contractor shall apply the exclusion criteria to the ontopic studies and update the Protocol as necessary during implementation. Titles and abstracts may be sufficient to screen some data sources for relevance, while full text review may be needed for other data sources. The screening will be done using DistillerSR, unless specified otherwise by TD, and the results will be uploaded into HERO. Following screening, the ICF discipline lead will check that the exclusion criteria were applied accurately and that the results were uploaded correctly into HERO.

Although uncertain, the WACOR may request that the contractor conduct this task for the new five TSCA risk evaluations. For costing purposes, the contractor shall assume that they will conduct full text screening for 1,000 on-topic references. The contractor shall also conduct full text screening supporting the five assessments of PBT chemicals.

When performing the screening, the contractor should communicate with the WACOR and technical contacts regularly to ensure that the screening process fits EPA's needs and that the WACOR and ICF Team Leader solve any issues in a timely manner. Additionally, if the actual time to review the references differs substantially from this estimate, or if the total number of studies to be categorized is higher or lower, the contractor shall contact the WACOR to determine the appropriate next steps.

#### **Deliverable Schedule:**

- The schedule for full-text screening literature and tagged references in HERO will be clarified by written TD from the WACOR.
- The contractor shall also provide documentation of the number of references screened and selected, including criteria-based rationale for including and excluding records. Note that the review of title and abstract may be sufficient to screen some data sources for relevancy, while full-text review may be needed for other data sources.
- The contractor shall also provide documentation flow diagram that graphically illustrates the number of titles, abstracts, and full articles reviewed during the literature search process

#### Task 3: Extract, Tabulate and Summarize Study Information

Since EPA must be transparent on the data considered and used for risk assessment purposes, the contractor shall extract and tabulate information by discipline for the suitable/usable studies identified in Task 2. The contractor shall work with the WACOR to identify the data elements to be included in the study tables and develop draft table templates and include them in the Protocol for EPA review and approval prior to extracting any information. Tabulated information will include, at a minimum, the study citation, the HERO identification number, and those data elements agreed by EPA. The data elements shall be documented.

The data tables will be used to evaluate and document the quality of the studies (see Task 2), as directed by TD from the WACOR, and will be designed to allow for evaluation consistent with the systematic review process. The WACOR may also ask, via TD, for study summaries in addition to the tabulated information, and this will be informed to the contractor by TD. The contractor shall revise the Protocol as necessary during implementation of this task.

The contractor shall perform a quality assurance check for the data tables prior to delivering them to the WACOR. Quality assurance checks will include, but not be limited to, comparing table entries and/or data elements in tables to information from the original publication and checking conversions as appropriate (e.g., ppm to mg/m³). The quality assurance check will be performed by a scientist that was not involved in the initial development of the table being reviewed.

The WACOR may request the contractor to do this task by written TD. For purposes of estimating costs for this work assignment, the contractor shall assume data extraction for 200 studies for estimating costs.

**Deliverable Schedule**: The schedule for the data tables will be clarified by written TD from the WACOR.

#### Task 4: Evaluate the Reliability of Studies

Following the screening for relevance, the contractor shall screen studies for reliability to determine whether the information is of appropriate quality to be used in the assessment (either for quantitative assessment or as supporting studies used in a WOE evaluation). The contractor may also document study evaluations in the tables developed in Task 3. As necessary, the contractor shall provide and manage experts to perform this task done in the previous ICF contract EP-C-14-001 WA 4-103.

EPA will provide the evaluation strategies that the contractor shall use for the reliability screening by discipline to support the prioritization process. However, the WACOR may ask the contractor to develop and/or refine an approach for conducting the reliability screening if needed. Study quality evaluations should be independent of considerations regarding the direction or magnitude of study results. The contractor may also conduct a first-tier data evaluation that will allow EPA to develop the conceptual model and analysis plan. The WACOR will issue chemical-specific TD to specify the level of data review and summarization.

The contractor shall provide the results of the data quality screening to the WACOR for review. The WACOR will determine which studies will be acceptable for use and communicate decision to contractor before moving to next step.

<u>Deliverable Schedule</u>: The WACOR will issue written TD (from the WACOR) clarifying the schedule for the data tables incorporating the results of the evaluation in Task 4

**Task 5: Activities Supporting the Integration of Information and Other Technical Support**Based on the reliable studies identified in Task 4, the contractor shall provide support for the following activities related to data integration:

- 1) <u>Evidence tables</u>: The contractor shall prepare tables that summarize results from studies (e.g., toxicological studies, exposure studies) identified in Task 4 consistent with guidance from WACOR and technical contacts. The contractor shall also conduct quality assurance (QA) checks of summary tables developed by experts. As necessary, the contractor shall provide and manage experts to perform this task.
- 2). Graphical <u>displays:</u> The contractor shall prepare graphical displays of results from studies identified by the WACOR. The types or formats of the graphical presentation shall be discussed between the WACOR, EPA technical contacts and the contractor. The contractor shall provide expertise to develop or modify graphical displays as needed. The contractor shall also conduct quality assurance (QA) checks of the data used to generate graphical displays. As necessary, the contractor shall provide and manage experts to perform this task.
- 3) Integrated reports: The contractor shall provide written, integrative reviews of the results of the studies using a WOE approach. The contractor shall analyze the entire body of data taking into consideration quality, consistency, relevancy, coherence and biological plausibility. Because OPPT uses WOE determinations to support its chemical risk evaluations, the contractor shall document the procedures or methods used to weigh the evidence and the basis for the WOE conclusion or recommendation. This is a requirement under the amended TSCA. The contractor shall provide written outline(s) to the WACOR for review prior to beginning the written integrated review. The contractor shall participate in telephone meetings as needed with the WACOR. The contractor shall develop a draft and a final report to be reviewed and approved by the WACOR. The contractor shall also match the EPA Software (currently Microsoft Office365 Pro Plus, EndNote 7, HERO, LitCiter and Adobe Pro 11) for drafting and creating a corresponding 508-compliant PDF with "HERO Links" in the report.
- 4) Other support: The contractor shall address other issues that may arise within the context of the review of studies supporting OPPT's technical products. These issues may pertain, but not limited to, the interpretation of specific results in toxicological studies, synthesis and dose-

response analysis of toxicological data, and issues pertaining to other disciplines (e.g., exposure, fate, engineering and ecotoxicology) or risk assessment issues (e.g., method development for new chemical risk evaluations) supporting OPPT's technical products under TSCA. As necessary, the contractor shall provide and manage experts to perform this task.

<u>Deliverable Schedule</u>: The deliverable schedule will vary depending on the subtask(s) and chemical, and will depend on the amount and complexity of the information to be evaluated/summarized. The schedule will be clarified within written TD from the WACOR

#### Task 6: Updates to literature search

The contractor shall perform literature search updates at regularly scheduled intervals during assessment development (i.e., through release of final risk assessment) and at least once after external peer review, if applicable. The interval (i.e., number of months) between literature search updates shall be determined in consultation with the WACOR. The literature search strategy shall be consistent with the strategy for the initial literature search and pertinent SOPs. The contractor shall add new references to HERO, tag references consistent with existing tags in HERO, and document the updated literature search strategy and findings.

If questions arise during the literature search and screening task (e.g., difficulties in narrowing down the number of "hits" from the search, questions about the relevance of certain types of papers or topics, retrieval of difficult to obtain documents or foreign language papers), the contractor shall contact the WACOR for further consultation.

<u>Deliverable Schedule</u>: The WACOR will issue written TD clarifying the schedule for the updates to the literature search conducted in Task 1.

#### **SCHEDULE OF DELIVERABLES:**

The contractor shall ensure that all 508 compliant documents developed in all tasks outlined in this work assignment will align with EPA's 508 compliance checks (keywords, titles, tables, tags, etc.). The contractor is responsible for maintaining and utilizing the same version of Adobe as the EPA for purposes of developing and maintaining 508 compliant documents. To the extent practical, documents which are developed for this work assignment, and are to be 508 compliant should be designed to be such from their inception, minimizing the effort for conversion and maximizing 508 compliance quality assurance.

Tasks	Deliverables
0- Work Plan and Monthly Progress Reports	Per contract requirements
1 - Literature Search	To be clarified in written TD.
2 - Screen literature for suitability/utility	To be clarified in written TD.
3- Tabulate and Summarize Study Information	To be clarified in written TD.
4- Evaluate the Reliability and Relevance of Studies	To be clarified in written TD.
5- Activities Supporting the Integration of	To be clarified in written TD.
Information and Other Technical Support	
6- Updates to Literature Search	To be clarified in written TD.

#### **CONFERENCE/MEETING GUIDELINES AND LIMITATIONS:**

The contractor shall immediately notify the EPA Contracting Officer, CL COR and WACOR of any anticipated event involving support for a meeting, conference, workshop, symposium, retreat, seminar or training that may potentially incur \$20,000 or more in cost during performance. Conference expenses are all direct and indirect costs paid by the government and include any associated authorized travel and per diem expenses, room charges for official business, audiovisual use, light refreshments, registration fees, ground transportation and other expenses as defined by the Federal Travel Regulations. All outlays for conference preparation should be included, but the federal employee time for conference preparation should not be included. After notifying the WACOR of the potential to reach this threshold, the contractor shall not proceed with the task(s) until authorized to do so by the Contracting Officer.

**TRAVEL:** No travel is anticipated for the performance period.

**SPECIAL REPORTING REQUIREMENTS:** The contractor shall discuss the progress of the Work Assignment and any issues in periodic teleconference calls, approximately on a bi-weekly basis (every other week) with the WACOR. The WACOR will schedule these teleconference calls.

**Confidential Business Information**: The contractor shall not handle confidential business information under this WA.

#### **NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT:**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or WA, the contractor shall immediately contact the Contract-Level COR, WACOR or CO.

## Appendix A: Supporting information on High Priority candidates

## High-Priority Candidates with available identifiers (e.g., CAS #, Chemical Name(s))

## [an Excel or csv file/table as needed]

## 75 Remaining chemicals from the 2014 Work Plan List

	Chemical Name	CASRN	DSSToxID as of 6/15/18
1	Acetaldehyde	75-07-0	DTXSID5039224
2	Acrylonitrile	107-13-1	DTXSID5020029
3	tert-Amyl methyl ether	994-05-8	DTXSID8024521
4	Antimony & Antimony Compounds**	Category	DTXSID30872414
5	Arsenic & Arsenic Compounds	Category	DTXSID90872415
6	Barium Carbonate	513-77-9	DTXSID1029623
7	Benzenamine	62-53-3	DTXSID8020090
8	Benzene	71-43-2	DTXSID3039242
9	Bisphenol A (BPA)	80-05-7	DTXSID7020182
10	1,3-Butadiene	106-99-0	DTXSID3020203
11	Butanamide, 2,2'-[(3,3'- dichloro[1,1'-biphenyl]- 4,4'-diyl)bis(azo)]bis[N- (4-chloro-2,5 - dimethoxyphenyl)-3-oxo-(Pigment Yellow 83)	5567-15-7	DTXSID1021453
12	Butanamide, 2-[(4- methoxy-2- nitrophenyl) azo]-N-(2- methoxyphenyl)-3-oxo- (Pigment Yellow 65)	6528-34-3	DTXSID0052336
13	Butyl benzyl phthalate (BBP) - 1,2- Benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester	85-68-7	DTXSID3020205
14	4-sec-Butyl-2,6-di-tert- butylphenol	17540-75-9	DTXSID8029315
15	Cadmium & Cadmium Compounds	Category	DTXSID10872417

16	Chromium & Chromium Compounds**	Category	
17	Cobalt & Cobalt Compounds**	Category	DTXSID30872419
18	Creosotes	8001-58-9	DTXSID2023987
19	Cyanide Compounds (Limited to dissociable compounds)	Category	DTXSID40872420
20	Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)	84-74-2	DTXSID2021781
21	o-Dichlorobenzene	95-50-1	DTXSID6020430
22	p-Dichlorobenzene	106-46-7	DTXSID1020431
23	3,3'-Dichlorobenzidine	91-94-1	DTXSID6020432
24	3,3'-Dichlorobenzidine dihydrochloride	612-83-9	DTXSID1020433
25	1,1-Dichloroethane	75-34-3	DTXSID1020437
26	1,2-Dichloroethane	107-06-2	DTXSID6020438
27	trans-1,2- Dichloroethylene	156-60-5	DTXSID7024031
28	1,2-Dichloropropane	78-87-5	DTXSID0020448
29	Dicyclohexyl phthalate	84-61-7	DTXSID5025021
30	Di-ethylhexyl phthalate (DEHP) - (1,2- Benzene- dicarboxylic acid, 1,2- bis(2- ethylhexyl) ester)	117-81-7	DTXSID5020607
31	Di-isobutyl phthalate (DIBP) - (1,2- Benzene- dicarboxylic acid, 1,2- bis- (2methylpropyl) ester)	84-69-5	DTXSID9022522
32	Di-isodecyl phthalate (DIDP) - (1,2- Benzene- dicarboxylic acid, 1,2- diisodecyl ester)	26761-40-0	DTXSID4025082
33	Di-isononyl phthalate (DINP) - (1,2- Benzene- dicarboxylic acid, 1,2- diisononyl ester)	28553-12-0	DTXSID4022521
34	1,2-Dimethoxyethane (Monoglyme)	110-71-4	DTXSID0025286

35	2-Dimethylaminoethanol	108-01-0	DTXSID2020505
36	Di-n-octyl phthalate (DnOP) - (1,2- Benzene- dicarboxylic acid, 1,2- dioctyl ester)	117-84-0	DTXSID1021956
37	Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,5,5- tetramethyl-2- naphthalenyl)- ***	54464-59-4	DTXSID5052200
38	Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8- tetramethyl-2- naphthalenyl)- ***	54464-57-2	DTXSID7031290
39	Ethanone, 1- (1,2,3,4,6,7,8,8a- octahydro- 2,3,8,8- tetramethyl-2- naphthalenyl)-	68155-67-9	DTXSID6041923
40	Ethanone, 1- (1,2,3,5,6,7,8,8a- octahydro- 2,3,8,8- tetramethyl-2- naphthalenyl)-	68155-66-8	DTXSID9052397
41	Ethylbenzene	100-41-4	DTXSID3020596
42	Ethylene dibromide	106-93-4	DTXSID3020415
43	bis(2-Ethylhexyl) adipate	103-23-1	DTXSID0020606
44	2-Ethylhexyl 2,3,4,5- tetrabromobenzoate (TBB)	183658-27-7	DTXSID9052686
45	bis(2-Ethylhexyl) - 3,4,5,6- tetrabromophthalate (TBPH)	26040-51-7	DTXSID7027887
46	Formaldehyde	50-00-0	DTXSID7020637
47	2,5-Furandione	108-31-6	DTXSID7024166
48	1-Hexadecanol	36653-82-4	DTXSID4027991
49	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222-05-5	DTXSID8027373
50	2-Hydroxy-4-(octyloxy) benzophenone	1843-05-6	DTXSID9027441

51	Lead & Lead Compounds**	Category	DTXSID00872421
52	Long-chain chlorinated paraffins (C18-20)	Category	DTXSID60872422
53	Medium-chain chlorinated paraffins (C14-17)	Category	DTXSID20872423
54	4,4'-Methylene bis(2- chloroaniline)	101-14-4	DTXSID5020865
55	4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	79-94-7	DTXSID1026081
56	Molybdenum and Molybdenum Compounds**	Category	DTXSID80872424
57	Naphthalene	91-20-3	DTXSID8020913
58	2-Naphthalenecarboxylic acid, 4-[(4-chloro-5-methyl-2-sulfophenyl) azo]-3-hydroxy-, calcium salt (1:1) - (Pigment Red 52)	17852-99-2	DTXSID2066270
59	Nickel & Nickel Compounds**	Category	DTXSID40872425
60	N-Nitroso- diphenylamine	86-30-6	DTXSID6021030
61	Nonylphenol and Nonylphenol Ethoxylates (NP/NPEs)	Category	
62	Octamethylcyclotetra- siloxane (D4)	556-67-2	DTXSID7027205
63	4-tert-Octylphenol (4-(1,1,3,3- Tetramethylbutyl)- phenol)	140-66-9	DTXSID9022360
64	p,p'- Oxybis(benzenesulfonyl hydrazide)	80-51-3	DTXSID7026499
65	Phosphoric acid, triphenyl ester (TPP)	115-86-6	DTXSID1021952
66	Phthalic anhydride	85-44-9	DTXSID2021159
67	Styrene	100-42-5	DTXSID2021284
68	Tribromomethane (Bromoform)	75-25-2	DTXSID1021374
69	1,1,2-Trichloroethane	79-00-5	DTXSID5021380

70	Triglycidyl isocyanurate	2451-62-9	DTXSID4026262
71	Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	DTXSID5021411
72	Vinyl chloride	75-01-4	DTXSID8021434
73	m-Xylene	108-38-3	DTXSID6026298
74	o-Xylene	95-47-6	DTXSID3021807
75	p-Xylene	106-42-3	DTXSID2021868

<sup>\*\*</sup>Includes substances that have multiple Work Plan metal compounds (e.g. "Cobalt molybdenum nickel oxide (CoMo2NiO8)")

<sup>\*\*\*</sup>Two PBT chemicals met the TSCA section 6(h) criteria; however, manufacturers for these substances submitted timely requests to EPA for risk evaluations (Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl) and Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)).

## Appendix B: Supporting information on endpoints/information/data related to disciplines

## To be revised under consultation with EPA staff

	Use Information
SIDS	Chemical Quantity
Elements/Disciplines	
Pchem Props	Melting Point
	Boiling Point
	Density (for inorganics)
	Vapor Pressure
	Octanol-Water Partition Coefficient
	Water solubility
	Dissociation constant(s) in Water
	Redox Potential (for inorganics)
Fate	Photodegradation
Tute	Thotoucgraduation
	Stability in Water (Hydrolysis)
	Transport and Distribution between
	Environmental Compartments
	(mackay fugacity model)
	Aerobic Biodegradation (Ready and
	Inherent)
	Bioaccumulation (optional)
Есо Тох	Fish Acute
	Daphnid Acute

	Algal Grown Inhibition
	Chronic Tox – most sensitive species in acute
	Terrestrial Tox (optional/if available)
	Sediment Tox (optional/if available)
Health Tox	Acute Tox (oral, dermal or inhalation, depending on relevant exposure routes)
	Acute Skin Irritation/Corrosion (optional)
	Acute Eye Irritation/Corrosion (optional)
	Skin Sensitization (option/if available)
	Repeated Dose Tox (relevant exposure pathways)
	Genetic Tox-In vitro; TWO endpoints
	Genetic Tox-In vivo (if one of the in vitro is positive)
	Repro Tox-Fertility (OECD 415/416/421/422)
	Dev Tox-Pre & Post natal (OECD 414/421/422)
	Neurotox (optional)
	Carcinogenicity or Chronic-2 yr (optional)
Exposure	Experience with Human Exposure (workplace exposure conce; indoor environment conc; frequency, duration, etc.)

EPA			U	United States Environmental Protection Agency Washington, DC 20460						Work Assignment Number 3-14				
				Work Assignment					Other X Amendment Number:					
Contract I	Number			Contract Period 11/01/2016 To 06/30/2020					Title of Work Assignment/SF Site Name					
EP-C-	16-01	1							Support for OPPTs Chemical Pri					
Base Option Period Number 3  Contractor Specify Section and paragraph of														
ICF Incorporated, L.L.C. 2.0,3.0,3.1,3.3,3									3.4,3.5,3.8,4.0					
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Comments	s:													
Stop Work Issued on 3-14. The contractor shall cease all work and incur no further charges on this work assignment. Effective Immediately.														
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								Pho	Phone Number: 202-564-1576					
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Project Of	ficer Nam	e Shirley	Harris	on		<b>V</b>	•		Branch/Mail Code:					
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	on:	J							Phone Number: 513-487-2036					
	(Signature) (Date)								FAX Number:					

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EPA		Work As	ssignment			Other Amendment Number:					
Contract Number	Cor	ntract Period 11/	'01/2016 <b>To</b>	06/30/:	2020	Title of Work Assignment/SF Site Name					
EP-C-16-011	Bas	se	Option Period Nur	mber 3		Lit Search f	for SDWA Ac	ctivities			
Contractor			191		•	of Contract SOW					
ICF Incorporated,	L.L.C.		2.1-	-2.3, 2.5	5-2.7, 2	7, 2.9-2.10, 3.1, 3.8, 4.1-4.3					
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. <u></u>						Phone Number: 513-487-2853					
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# PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-16-011 WORK ASSIGNMENT # 3-16

TITLE: Literature Searches for Various Chemicals to Support Safe Drinking Water Act (SDWA) Activities

#### WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

Barbara Soares (Mail Code 4303)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (HECD)
United States Environmental Protection Agency (USEPA)
1200 Pennsylvania Avenue NW
Washington DC, 20460
Telephone #:202-566-1437

E-mail address: soares.barbara@epa.gov

#### ALTERNATE WACOR:

Jamie Strong (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (HECD)
United States Environmental Protection Agency (USEPA)
1200 Pennsylvania Avenue NW
Washington DC, 20460
Telephone #:202-566-0056 Fax#: 202-566-1140

E-mail address: strong.jamie@epa.gov

LOE Hours: 4,800 hours

PERIOD OF PERFORMANCE: July 1, 2019 through June 30, 2020

CONTRACT PWS: 2.1 thru 2.3, 2.5 thru 2.7, 2.9 and 2.10, 3.1, 3.6, 3.8, 4.1 thru 4.3

\*\*Note: No Confidential Business Information data will be needed in the course of this work assignment.

BACKGROUND: The Human Health Risk Assessment Branch (HHRAB) of the Office of Science and Technology (OST) works closely with the Office of Ground Water and Drinking Water (OGWDW) in developing risk assessment documents which support the derivation of maximum contaminant level goals (MCLGs) and health advisories for contaminants found in drinking water as part of statutory requirements outlined in the Safe Drinking Water Act (SDWA).

**PURPOSE:** The purpose of this work assignment (WA) is to provide technical support services to HECD for developing literature search strategies, conducting literature searches and potentially assisting in the systematic review of literature searches for various:

- regulated chemicals identified for regulatory revision as part of Six Year Review 4
- unregulated chemicals which may become regulated through regulatory revision as part of Six Year Review 3 or Regulatory Determination 4
- unregulated chemicals contained on the candidate contaminant list (CCL) 4 and 5 or
- unregulated and emerging chemicals of concern identified as needed

This WA is intended to support literature searches on various contaminants as the need arises. HHRAB often requires short-term and quick-response work to revise or amend analyses for specific chemicals, or to initiate exploratory work on a new chemical. This work assignment directly supports HECD mission to produce and publish scientifically sound, and implementable guidance and criteria to protect human health from contaminants found in drinking water. Specifically, this work assignment includes tasks to perform literature searches for chemicals identified as potentially posing a risk to human health through the ingestion of drinking water.

QUALITY ASSURANCE: The tasks in this work assignment require the use of existing data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data under EPA Contract EP-C-16-011, in order to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the March 2017 pQAPP for existing data. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment (WA)-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

#### PERFORMANCE WORK STATEMENT (PWS):

Under this PWS, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will specify deadlines for delivering drafts and final work products. An initiating TD will identify specific Tasks (enumerated below) to be performed.

The contractor shall provide personnel who are proficient with the software tools Microsoft Excel, Endnote, and, when appropriate, systematic review tools such as Distiller and HAWC.

The contractor shall prepare documents in the format specified in the TD for each chemical. It is possible that the scope of the systematic review and the deliverable may change depending on the chemical. Documents shall be technically edited for format and grammar before being delivered to the WACOR.

Deliverables shall be provided to the WACOR in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents). The WACOR requests that all Excel spreadsheets also be delivered in .csv format.

The contactor shall develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, analyses, used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contactor will provide access to this internal documentation upon request by the WACOR or the Contract-Level COR.

The contractor shall submit drafts of all deliverables to the WACOR for review prior to submission of the final product. These drafts shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources and data that support any conclusions and recommendations. The contractor shall incorporate all WACOR comments (and peer review comments, where applicable) into all final deliverables, unless otherwise agreed upon by the WACOR.

#### TASK 1: Work Plan and Monthly Progress Reports

#### Task 1.1 Work Plan

The contractor shall develop a detailed work plan and cost estimate for each task outlined in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Deliverables: Conference call Due Date: 2 weeks after receipt of WA

#### Task 1.2 Monthly Progress Reports

This task includes monthly progress and financial reports. The monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

As described in the Quality Assurance Section, the contractor must comply with the ICF March 2017 approved pQAPP for the use of seconddary data and, if applicable, application of peer reviewed existing models. The monthly progress report shall indicate, in a separate QA section, whether significant project-specific QA issues have been identified and how they are being resolved.

Deliverables: Monthly progress report Due Date: Per contract requirements

#### Task 1.3 Information Quality Guidelines (IQG)

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (IQG) (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information. The contractor shall complete the Office of Water (OW) IQG Checklist as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the OW IQG checklist. The WACOR will provide the checklist to the contractor. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed meet the requirements of the OW's IQG checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report.

Deliverables: IQG memo Due Date: End of the work assignment

TASK 2: Systematic Literature Search

#### Task 2.1 Literature Search Strategy and Evaluation Criteria Development

Literature searches will be completed for numerous (approximately 50-75) chemicals. Under this PWS, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will specify deadlines for delivering drafts and final work products. A TD initiation meeting between the contractor and WACOR shall take place no later than one week after the TD is received.

The contractor shall develop literature search strategies as specified in each TD. Each TD will require a literature search strategy for each chemical in accordance with the ICF March 2017 pQAPP for existing data.

Specifically, the literature searches should address all literature related to health effects in animals and humans resulting from acute, subchronic, and chronic exposure durations, and from inhalation, oral, dermal, and injection exposure studies. The contractor shall identify epidemiological studies and in vitro studies related to mechanism of action. The contractor shall also identify data specifically useful for addressing risks to children and other susceptible populations (e.g., the elderly, nursing and pregnant women). The contractor shall also include studies of absorption, distribution, metabolism, and elimination; and models useful for dose- response assessment such as dosimetry models and physiologically-based pharmacokinetic (PBPK) models. The literature searches should also address all literature related to physical and chemical properties, occurrence and environmental fate.

The health effects support documents for PFOA and PFOS should serve as an example to structure the search for this information (<a href="https://www.epa.gov/sites/production/files/2016-05/documents/pfoa">https://www.epa.gov/sites/production/files/2016-05/documents/pfoa</a> hesd final 508.pdf and <a href="https://www.epa.gov/sites/production/files/2016-05/documents/pfoa">https://www.epa.gov/sites/production/files/2016-05/documents/pfoa</a> hesd final 508.pdf).

In addition to the traditional search engines such as PubMed, Toxline, Web of Science and other databases, the literature search strategy shall also include searches for relevant domestic and international non-periodical literature, such as books, technical reports, monographs, and conference and symposium proceedings prepared by select committees or bodies (e.g., such as those convened by the National Academy of Sciences or the World Health Organization). Additionally, include searches of secondary sources such as Registry of Toxic Effects of Chemical Substance (RTECS), National Toxicology Program (NTP), National Cancer Institute (NCI), National Institute for Environmental Health Sciences (NIEHS), National Center for Toxicological Research (NCTR), TSCA Test Submissions (TSCATS) database, etc., for unpublished or interim research reports relevant to the subject of the search. Appropriate EPA health assessment documents, guidelines, and other secondary sources such as Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles shall also be used to identify relevant literature.

At the TD initiation meeting, the contractor and EPA WACOR will discuss the elements to be included in the literature search strategy as well as the strategy to tag the literature. The contractor shall deliver the literature search strategy as a Word document, two weeks after the task initiation meeting. The WACOR will provide feedback as necessary and will instruct the contractor when to initiate the literature searches.

Deliverable 1: Technical direction (TD) initiation meeting

Due Date: Within one week of receipt of TD

Deliverable 2: Literature search strategy document Due Date: Two weeks after TD initiation meeting

### Task 2.2 Conduct Literature Searches and Provide Documentation

Once the literature search strategy has been approved by the WACOR, the contractor shall conduct the literature searches, remove duplicates and compile the results. The references shall be tagged as relevant, not relevant, and unsure. As work progresses on this task, the Contractor shall periodically consult with the EPA WACOR to discuss the appropriate characterization of any studies for which inclusion/exclusion is unclear.

The contractor shall develop Excel spreadsheets with a tab for:

- 1) relevant studies
- 2) studies that were found in the search, but were deemed not relevant and the reasons why they were not relevant, and
- 3) studies the contractor could not determine as relevant or not relevant for further review. The Excel spreadsheets should be completed so that it is compatible for .csv to be uploaded into other software programs such as Distiller or HAWC.

The contractor shall deliver the spreadsheets for the EPA WACOR's review 1-3 weeks after the completion of the literature search, depending on the number of references compiled.

The WACOR will work in collaboration with the contractor to determine if the studies on tab 3 are relevant for further review. The contractor shall update the spreadsheet once decisions are made about tab 3 and the WACOR approves the other tabs.

Additional documentation of the literature searches shall be added into the Word files containing the search and tagging strategies for the chemical created in Task 1. This additional documentation shall contain at a minimum search strings, results (number of citations), and date of searches. It should outline the specific databases examined, keywords employed, number of hits, and any limits of the search. In addition, the number of relevant papers for each chemical should be identified by the predetermined tags where possible (e.g., human, animal toxicity, toxicokinetics, PBPK modeling, mechanism studies, etc).

Deliverable 1: Draft literature search results in a three-tabbed excel spreadsheet Due Date: 1-3 weeks after test screening results meeting

Deliverable 2: Finalized literature search results in a three-tabbed excel spreadsheet Due Date: 1 week after WACOR approval of the draft

### Task 3: Retrieval of Relevant Literature

The contractor shall retrieve all pertinent references according to ICF SOP for literature retrieval (SOP No. ICF-7006) The contractor shall first discuss with the WACOR about prioritizing the references needed. For studies deemed insufficient, the contractor shall collate abstracts only. The contractor shall communicate as necessary with the WACOR regarding difficult to obtain references and foreign language documents. EPA will make a determination as to whether or not to pursue retrieval of such documents. Task 2 deliverable, i.e., copies of relevant references, shall be provided in electronic format (generally in pdf format).

Deliverable 1: PDFs of approved references

Due Date: 1-2 weeks after WACOR approval of the completed literature searches

### Task 4: General Support of Systematic Review

The contractor shall, based on written technical direction given by the WACOR, provide support in tagging relevant studies through Distiller and/ or in extracting data from relevant references into HAWC. The contractor may need to work with Health and Environmental Research Online (HERO) staff to upload references onto HERO pages. A weekly update call with the WACOR will be required for this work assignment, as needed. Details on the scope and LOE will be provided by the WACOR through written technical direction, as further information becomes available.

### Task 5: General Project Support

The contractor shall, based on written technical direction given by the WACOR, provide support on specific data analyses may be required for briefings and/or communication materials. Such analyses would be based on written technical direction provided by the WACOR. These analyses are generally to support decision-making and usually have a defined scope to address specific risk management questions. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The WACOR may request the contractor to participate in and/or conduct briefings. A weekly update call with the WACOR may be required for this work assignment, on an as needed basis.

### General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

**Travel:** No travel is anticipated under this task assignment.

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Per contract requirements
Progress Reports	1.2	Per contract re
Information Quality Guidelines	1.3	Discuss with WACOR within 14 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: Systematic Literature Search		
Literature Search Strategy and Evaluation Criteria Development	2.1	Throughout the period of performance. TD initiation meeting to be held within 7 calendar days of receipt of a TD. Subsequent meetings to be held roughly weekly, as needed. The literature search strategy for each TD is due to WACOR within 14 calendar days of the TD initiation meeting.
Conduct Literature Searches and Provide Documentation	2.2	Literature searches conducted upon WACOR's approval of the literature search strategy. Draft excel spreadsheets documenting the results of the literature searches are due 7 – 21 days after approval of the literature search strategy, depending on the number of results. Meetings to be held roughly weekly, as needed, to discuss progress and results. Final literature search Excel spreadsheets due 7 days after WACOR approval of draft spreadsheets.
Task 3: Retrieval of Relevant Literature		
PDFs of approved references	3.1	1-2 weeks after WACOR confirmation of approved and relevant literature
Task 4: General Support of Systematic Review		
Support tagging of literature in Distiller and/or extraction of data from relevant literature in HAWC	4.1	On-going
		On-going

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Work Assignment Manager Name Da	india Sodies					Branch/Mail Code:  Phone Number: 202-566-1437			
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# PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-16-011 WORK ASSIGNMENT #3-16 Amd 1

TITLE: Literature Searches for Various Chemicals to Support Safe Drinking Water Act (SDWA) Activities

### WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

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E-mail address: <a href="mailto:strong.jamie@epa.gov">strong.jamie@epa.gov</a>

PERIOD OF PERFORMANCE: Date of issuance through June 30, 2020

CONTRACT PWS: 2.1 thru 2.3, 2.5 thru 2.7, 2.9 and 2.10, 3.1, 3.6, 3.8, 4.1 thru 4.3

\*\*Note: No Confidential Business Information data will be needed in the course of this work assignment.

PURPOSE OF AMENDMENT: The purpose of amendment is to add new subtasks to support Task #4 (General Support of Systematic Review). Specifically, these new subtasks will provide support to develop a rapid systematic review protocol to support the Candidate Contaminant List 5 (CCL5) and Six Year Review 4 (SYR4). HHRAB is anticipating initiating a pilot where up to 10 rapid systematic reviews would be conducted to develop and test the rapid systematic review protocol. Ultimately, HHRAB would want to use the rapid systematic review protocol developed under this amendment on all CCL 5 contaminants (approximately 250) and potentially for all regulated contaminants considered under Six Year Review 4 (approximately 70 contaminants). This amendment is intended to be supported by the LOE in WA 3-16. No additional LOE will be needed to complete the work outlined in this amendment. There is enough funding in this work assignment to cover the amendment. No revised cost estimate is required.

### Task 4: General Support of Systematic Review

The contractor shall, based on written technical direction given by the WACOR, provide support in tagging relevant studies through Distiller and/or in extracting data from relevant references into HAWC. The contractor may need to work with Health and Environmental Research Online (HERO) staff to upload references onto HERO pages. A weekly update call with the WACOR will be required for this work assignment, as needed. Details on the scope and LOE will be provided by the WACOR through written technical direction, as further information becomes available.

### Task 4A: Develop Rapid Systematic Review Protocol

As stated above, the purpose of this subtask is to develop a rapid systematic review protocol to support CCL5, and potentially Six Year Review 4, using systematic review tools such as SWIFT-Review, SWIFT-Active Screener, Distiller and HAWC.

The goals of the literature searches and subsequent rapid systematic reviews are to:

- 1.) Identify health effects information (epidemiological, toxicological studies and PBPK models) published since the identified health assessments using systematic review tools such as SWIFT-Review, SWIFT-Active Screener and Distiller.
- 2.) Extract data from relevant studies in HAWC which could potentially help to derive toxicity numbers.

The following tasks are outlined in more detail in Appendix A. HRRAB realizes that developing the rapid systematic review process will be iterative and may not look exactly as described in Appendix A or in the tasks below. During this developmental phase, HHRAB asks that ICF check-in with the WACOR before and after each task.

Task 4A.1: Execute Literature Searches in SWIFT-Review

The following contaminants will be used to develop/pilot the rapid systematic review protocol:

DTXSID number	Chemical Name
DTXSID5036761	Lithium
DTXSID2021995	DEET (pesticide)
DTXSID2024169	Manganese
DTXSID0032497	Triclopyr (pesticide)
DTXSID7023982	Chromium (VI) ion
DTXSID5021758	Tris(2-butoxyethyl) phosphate

Begin by checking if the chemical is a pesticide by checking if it has an entry in the PCCL5 file with a source listed as "fifra" – compounds with this entry are included in the list of registered pesticide active ingredients. If the chemical is a pesticide, check for an assessment by EPA's Office of Pesticides

using this link (<a href="https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1::">https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1::</a>) and following Step 1 outlined in Appendix A. Next, check for existing assessments in PCCL Excel spreadsheet using DTXSID number (not chemical name). Health assessments with records in the PCCL5 file include EPA IRIS, EPA PPRTV, Minnesota Department of Health (MN DOH), California EPA (OEHHA), Health Canada, ATSDR, WHO, and EPA Health Advisories summarized in the Drinking Water Standards and Health Advisory Tables (DWSHA). EPA's Human Health Benchmark's for Pesticides (HHBPs) are included in the PCCL file. Though these benchmarks are not in themselves health assessments, they are derived using existing health assessments from EPA's Office of Pesticides. The HHBP website is a helpful way to find links to OPP assessments. If there is no OPP assessment or other assessment in the PCCL database, the literature search will be date unlimited. If there is an assessment, the beginning date of the literature search will be one year prior to the assessment publication date. Use SWIFT-Review to execute the literature search in PubMed by following the Step 3 in Appendix A. Save the results of the PubMed search in an Excel file as described in Step 3 of Appendix A.

# Task 4A.2. Use SWIFT-Review to filter literature search and SWIFT-Active Screener to tag relevant studies

Load the saved literature search results in SWIFT-Review and record the number of human and animal studies by using the evidence stream tool in SWIFT-Review (Step 4 of Appendix A). For this pilot study, only the animal evidence stream will be used. Follow Step 4 of Appendix A to select the studies in the animal evidence stream and send them to SWIFT-Active Screener. Once in SWIFT-Active Screener, create a form to match Appendix B and conduct the title and abstract screen for inclusion and exclusion based upon the criteria outlined in Step 5 of Appendix A and the template form in Appendix B. Tag the studies with as many supplemental tags as relevant.

### Task 4A.3. Retrieve PDFs for included studies

Work with the WACOR to retrieve relevant studies from either the Health and Environmental Research Online (HERO) librarians or following Task 3 of WA 3-16. If the studies are retrieved through HERO, HHRAB asks that the contractors send the list of included studies to <a href="https://example.com/HERO@epa.gov">HERO@epa.gov</a>, and work with the HERO librarians to collect the PDFs and upload them into Distiller or HAWC.

# Task 4A.4. Conduct Full Text Screen in Distiller (if needed) and/or Conduct Relevant Analyses in HAWC

Work with the WACOR to determine if a full text screening for inclusion or exclusion is necessary. A full text screen for inclusion/exclusion may be necessary if there are 50 or more studies retrieved as relevant. If the EPA WACOR decides a full text screening is necessary, the EPA WACOR will set up a project in Distiller and populate a form for the full text screen. HHRAB asks that ICF upload the full text PDFs to Distiller. Once the full text screen is complete, ICF shall upload included studies into HAWC for data extraction, study quality evaluation, and risk of bias characterization (where necessary).

If a full text review is not necessary (e.g., less than 50 studies are tagged as relevant), HHRAB asks that ICF upload all relevant PDFs into HAWC for data extraction, study evaluation and risk of bias characterization (where necessary). Work with the WACOR to decide how to conduct the study evaluation, what types of data need to be extracted from each study, and which studies need a risk of bias analysis.

### Task 4B. Execute Rapid Systematic Review Protocol on CCL5 Contaminants

Once the rapid systematic review protocol is established, ICF will work with the WACOR to complete rapid systematic reviews on the remaining CCL5 contaminants (approximately 245 contaminants). A task order will be sent to initiate this work and provide additional detail. EPA asks that the systematic reviews be completed in batches of 10-20 chemicals.

Task 4C. Execute Rapid Systematic Review Protocol on Six Year Review 4 Contaminants

Once the rapid systematic review protocol is established, ICF will work with the WACOR to complete rapid systematic reviews for all regulated contaminants considered under Six Year Review 4 (approximately 70 contaminants). A task order will be sent to initiate this work and provide additional detail and any modifications needed to the rapid systematic review protocol.

Travel: No travel is anticipated under this amendment.

Task	Milestones and Due Dates
Task 4: General Support of Systematic Review	
Task 4A: Develop Rapid Systematic Review Protocol	Rapid systematic review protocol developed and completed on 6 pilot contaminants <b>Due</b> : 6 weeks after initiation of Task 4A
Task 4B: Execute Rapid Systematic Review Protocol on CCL5 Contaminants	Rapid systematic review protocol completed for remaining CCL5 contaminants <b>Due</b> : TBD after completion of the rapid systematic review protocol; note that the December-January timeframe is in the draft schedule for CCL5 literature searches
Task 4C: Execute Rapid Systematic Review Protocol on Six Year Review 4 Contaminants	Rapid systematic review protocol completed for Six Year Review 4 contaminants <b>Due</b> : TBD after completion of the rapid systematic review protocol

### Appendix A: Rapid Systematic Review Protocol – Proposed Deliverable from ICF

# \*\*Note that HHRAB anticipates changes may need to be made to this deliverable as the rapid systematic review protocol is developed and piloted.

- 1. Check if the chemical is a pesticide and if EPA's Office of Pesticide Programs has an assessment
  - Search PCCL database using DTXSID number and look for if the compound has an entry with the source "fifra". This means that the compound is included on the list of registered pesticides and active pesticide ingredients and is a good indication that the compound will have an OPP assessment available.
  - If it is a pesticide, click this link: https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1::
  - o Type in the chemical name in the chemical name search bar and click go
  - Click on chemical name and click on Regulatory Actions tab
  - Identify any human health assessments in Document box:
    - Reregistration Eligibility Documents (REDs)
    - Interim Reregistration Eligibility Documents (iREDs)
    - tolerance Reassessment Eligibility Decision (tRED)
    - Health Effects Division Human Health Risk Assessments (HED HHRAs)
- 2. Check for existing assessments in PCCL database using DTXSID number (not chemical name)
  - If no assessment, use date unlimited search
  - If there is an assessment, the date used for beginning date of the literature search will be one year prior to the assessment publication date.
  - Assessments are defined as one of the following document types
    - ATSDR Toxicity Profile
    - CalEPA Public Health Goal
    - WHO Drinking Water Guideline
    - Health Canada Drinking Water Guideline
    - EPA Health Advisory or Health Effects Support Document (HESD)
    - EPA OP RED, iRED, tRED, or HED HHRAEPA IRIS Assessment
    - EPA PPRTV Assessment
- 3. Open SWIFT-Review
  - Click Tools, find chemical synonyms
  - o Type in chemical name or CAS number a list of synonyms will appear
    - Add this list of synonyms to the PECO Statement (see attachment A)
  - In the query that the computer generates, click the hyperlinked PMID text this will open a PubMed search window
  - Date limit the search (Publications dates custom range) based on the date of the last assessment
  - Click "sent to" send to file xml
    - Save file with dtxsid, name, date (day month year, 2 digits for day month and 4 for year)
      - For example: "dtxsid5036761 lithium 05072019.xml"
- 4. Filter Literature Search Results in SWIFT-Review
  - o Load reference file
  - Drawdown menu "Evidence Stream"
    - Record the number of animal studies and human studies in an Excel spreadsheet.
       Include a column for the DTXSID number, chemical name, # of animal studies and # of human studies
  - Select Animal in "Evidence Stream"
    - Select all studies in bottom half of screen (command a), right click, send to active viewer, new project, de-duplicate by title, name new project chemical name\_date
      - For example: "Lithium\_05072019"

- 5. Log in to SWIFT-Active Screener
  - Start new project
  - Make form to match the attached template (Attachment B)
    - Include if all of the following are true:
      - Mammalian model
      - Multiple treatment groups (> 1 dose group) and a control group
      - Subchronic exposure or chronic exposure (include if 28 days or more in rodent models), or include if study is targeting developmental or reproductive endpoints
      - Oral route of exposure (gavage, food or water)
      - Dose groups contain only the substance of concern, not mixtures
    - Exclude all other studies
    - Include studies if the abstract does not have enough information to know if the inclusion criteria are met (i.e., if you can't tell if the study qualifies, keep it in)
- 6. HERO (or the most efficient mechanism) for retrieving included studies
  - Work with EPA WACOR to determine how full text PDFs will be retrieved
- 7. Distiller, full text screen for relevancy
  - o Work with EPA WACOR to determine if a full text screening for inclusion/exclusion is necessary.
  - EPA WACOR will set up the Distiller project and populate the Distiller form to tag for relevance
- 8. HAWC for data extraction, study evaluation and risk of bias analyses
  - Work with EPA WACOR to determine what data to extract from each study, how to conduct the study evaluations and risk of bias analyses.

# **ATTTACHMENT A**

Replace the highlighted next with the appropriate info for each contaminant

# Table 1. PECO Statement for the PFOA

P	Human: Any population and lifestage (occupational or general population, including children and other sensitive populations).  Animal: Nonhuman mammalian animal species (whole organism) of any lifestage (including preconception, in utero, lactation, peripubertal, and adult stages).  In vitro/cell studies or in silico/modeling toxicity studies should be tagged as supplemental
E	Relevant forms: INSERT NAME HERE PFOA (CAS number 335-67-1). Other names: perfluorooctanoate, perfluorooctanoic acid, perfluoroctanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctanoic acid, Pentadecafluoro-1-octanoic acid, Pentadecafluoro-n-octanoic acid, Octanoic acid, pentadecafluoro-, Perfluorocaprylic acid, Pentadecafluorooctanoic acid, perfluoroheptanecarboxylic acid  Human: Any exposure to PFOA via oral routes. Other exposure routes, including inhalation, dermal or unknown/multiple routes, will be tracked during title and abstract screening and tagged as "potentially relevant supplemental information."  Animal: Any exposure to PFOA via oral routes. Other exposure routes, including inhalation, dermal, injection or unknown/multiple routes, will be tracked during title and abstract screening and tagged as "potentially relevant supplemental information." Studies involving exposures to mixtures will be included only if they include exposure to PFOA OR PFOS alone.
С	Human: A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of PFOA, or exposure to PFOA for shorter periods of time. Case reports and case series will be tracked as "potentially relevant supplemental information."  Animal: A concurrent control group exposed to vehicle-only treatment or untreated control.
o	All health outcomes (both cancer and noncancer).
PBPK Models	Studies describing physiologically-based pharmacokinetic (PBPK) models will be included

# Appendix B. Template form for SWIFT Active Reviewer

Table 1. Additional tags for studies not included during SWIFT active reviewer screening

Category	Evidence
Mechanistic studies	Studies reporting measurements related to a health outcome that inform the biological or chemical events associated with phenotypic effects, in both mammalian and non-mammalian model systems, including in vitro, in vivo (by various routes of exposure), ex vivo, and in silico studies. When possible, mechanistic studies will be sub-tagged as pertinent to cancer, non-cancer, or unclear/unknown.
Non-mammalian model systems	Studies in non-mammalian model systems, e.g., fish, birds, <i>C. elegans</i>
ADME and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion, including toxicokinetic studies. Such information may be helpful in updating or revising the parameters used in existing PBPK models.
Acute/short-term duration exposures	Animal studies of less than 28 days
Exposure characteristics	Exposure characteristic studies include data that are unrelated to toxicological endpoints, but which provide information on exposure sources or measurement properties of the environmental agent (e.g., demonstrate a biomarker of exposure).
Susceptible populations	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, lifestage, or genotype.
Mixture studies	Mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest.
Non-oral routes of exposure	Studies not addressing routes of exposure that fall outside the PECO scope, include inhalation and dermal exposure routes
Case studies or case series	Case reports and case series will be tracked as potentially relevant supplemental information.
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.

Table 2. Additional tags for studies that are included during SWIFT active reviewer screening

Category	Evidence
Animal repeat dose – chronic/cancer	

Animal repeat dose – reproductive/developmental	
Animal repeat dose – multigenerational	
Animal repeat dose subchronic	
Human epi study	
PBPK model	

EPA				United States Environmental Protection Agency Washington, DC 20460 Work Assignment					Work Assignment Number 3-16				
									Other X Amendment Number:				
Contract N	lumber			Contra	act Period 11/	01/2016 <b>To</b>	06/30/2	2020	Title of Wo	rk Assignn	nent/SF Site Nam	ne	
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Contractor							y Section and pa	ragraph of Co	ontract SOW				
ICF In	ncorp	orated,	L.L.C.			2.1-	-2.3, 2.5	5-2.7,	2.9-2.1	0, 3.1	, 3.8, 4.1	-4.3	
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Work Assign	nment M	anager Name	Barbara	Soar	ces			Bra	anch/Mail Co	ode:			
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		(Sign	ature)			(Date	)		X Number:				
Project Officer Name Shirley Harrison				Bra	anch/Mail Co	ode:							
								Ph	one Number	: 202-	566-1107		
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63									Phone Number: 513-487-2146				
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# PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-16-011 WORK ASSIGNMENT #3-16 Amd 2

TITLE: Literature Searches for Various Chemicals to Support Safe Drinking Water Act (SDWA) Activities

### WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

Barbara Soares (Mail Code 4303)

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United States Environmental Protection Agency (USEPA)

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Washington DC, 20460 Telephone #:202-566-1437

E-mail address: soares.barbara@epa.gov

### ALTERNATE WACOR:

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Telephone #:202-566-0056 Fax#: 202-566-1140

E-mail address: <a href="mailto:strong.jamie@epa.gov">strong.jamie@epa.gov</a>

LOE Hours: 2,305 hours

PERIOD OF PERFORMANCE: Date of issuance through June 30, 2020

CONTRACT PWS: 2.1 thru 2.3, 2.5 thru 2.7, 2.9 and 2.10, 3.1, 3.6, 3.8, 4.1 thru 4.3

\*\*Note: No Confidential Business Information data will be needed in the course of this work assignment.

PURPOSE OF AMENDMENT: The purpose of amendment is to revise the cost estimate, to add additional LOE in WA 3-16 to complete remaining rapid systematic reviews for Candidate Contaminant List 5 (CCL 5) contaminants under Task 4 in support of CCL5 and Six Year Review 4 (SYR4).

### Task 4: General Support of Systematic Review

The contractor shall, based on written technical direction given by the WACOR, provide support in tagging relevant studies through Distiller and/or in extracting data from relevant references into HAWC. The contractor may need to work with Health and Environmental Research Online (HERO) staff to upload references onto HERO pages. A weekly update call with the WACOR will be required

for this work assignment, as needed. Details on the scope and LOE will be provided by the WACOR through written technical direction, as further information becomes available.

### Task 4A: Develop Rapid Systematic Review Protocol

As stated above, the purpose of this subtask is to develop a rapid systematic review protocol to support CCL5, and potentially Six Year Review 4, using systematic review tools such as SWIFT-Review, SWIFT-Active Screener, Distiller and HAWC.

The goals of the literature searches and subsequent rapid systematic reviews are to:

- 1.) Identify health effects information (epidemiological, toxicological studies and PBPK models) published since the identified health assessments using systematic review tools such as SWIFT-Review, SWIFT-Active Screener and Distiller.
- 2.) Extract data from relevant studies in HAWC which could potentially help to derive toxicity numbers.

The following tasks are outlined in more detail in Appendix A. HRRAB realizes that developing the rapid systematic review process will be iterative and may not look exactly as described in Appendix A or in the tasks below. During this developmental phase, HHRAB asks that ICF check-in with the WACOR before and after each task.

Task 4A.1: Execute Literature Searches in SWIFT-Review

The following contaminants will be used to develop/pilot the rapid systematic review protocol:

DTXSID number	Chemical Name
DTXSID5036761	Lithium
DTXSID2021995	DEET (pesticide)
DTXSID2024169	Manganese
DTXSID0032497	Triclopyr (pesticide)
DTXSID7023982	Chromium (VI) ion
DTXSID5021758	Tris(2-butoxyethyl) phosphate

Begin by checking if the chemical is a pesticide by checking if it has an entry in the PCCL5 file with a source listed as "fifra" – compounds with this entry are included in the list of registered pesticide active ingredients. If the chemical is a pesticide, check for an assessment by EPA's Office of Pesticides using this link (<a href="https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1::">https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1::</a>) and following Step 1 outlined in Appendix A. Next, check for existing assessments in PCCL Excel spreadsheet using DTXSID number (not chemical name). Health assessments with records in the PCCL5 file include EPA IRIS, EPA PPRTV, Minnesota Department of Health (MN DOH), California EPA (OEHHA), Health Canada, ATSDR, WHO, and EPA Health Advisories summarized in the Drinking Water Standards and

Health Advisory Tables (DWSHA). EPA's Human Health Benchmark's for Pesticides (HHBPs) are included in the PCCL file. Though these benchmarks are not in themselves health assessments, they are derived using existing health assessments from EPA's Office of Pesticides. The HHBP website is a helpful way to find links to OPP assessments. If there is no OPP assessment or other assessment in the PCCL database, the literature search will be date unlimited. If there is an assessment, the beginning date of the literature search will be <u>one year prior</u> to the assessment publication date. Use SWIFT-Review to execute the literature search in PubMed by following the Step 3 in Appendix A. Save the results of the PubMed search in an Excel file as described in Step 3 of Appendix A.

# Task 4A.2. Use SWIFT-Review to filter literature search and SWIFT-Active Screener to tag relevant studies

Load the saved literature search results in SWIFT-Review and record the number of human and animal studies by using the evidence stream tool in SWIFT-Review (Step 4 of Appendix A). For this pilot study, only the animal evidence stream will be used. Follow Step 4 of Appendix A to select the studies in the animal evidence stream and send them to SWIFT-Active Screener. Once in SWIFT-Active Screener, create a form to match Appendix B and conduct the title and abstract screen for inclusion and exclusion based upon the criteria outlined in Step 5 of Appendix A and the template form in Appendix B. Tag the studies with as many supplemental tags as relevant.

### Task 4A.3. Retrieve PDFs for included studies

Work with the WACOR to retrieve relevant studies from either the Health and Environmental Research Online (HERO) librarians or following Task 3 of WA 3-16. If the studies are retrieved through HERO, HHRAB asks that the contractors send the list of included studies to <a href="https://example.com/HERO@epa.gov">HERO@epa.gov</a>, and work with the HERO librarians to collect the PDFs and upload them into Distiller or HAWC.

# Task 4A.4. Conduct Full Text Screen in Distiller (if needed) and/or Conduct Relevant Analyses in HAWC

Work with the WACOR to determine if a full text screening for inclusion or exclusion is necessary. A full text screen for inclusion/exclusion may be necessary if there are 50 or more studies retrieved as relevant. If the EPA WACOR decides a full text screening is necessary, the EPA WACOR will set up a project in Distiller and populate a form for the full text screen. HHRAB asks that ICF upload the full text PDFs to Distiller. Once the full text screen is complete, ICF shall upload included studies into HAWC for data extraction, study quality evaluation, and risk of bias characterization (where necessary).

If a full text review is not necessary (e.g., less than 50 studies are tagged as relevant), HHRAB asks that ICF upload all relevant PDFs into HAWC for data extraction, study evaluation and risk of bias characterization (where necessary). Work with the WACOR to decide how to conduct the study evaluation, what types of data need to be extracted from each study, and which studies need a risk of bias analysis.

### Task 4B. Execute Rapid Systematic Review Protocol on CCL5 Contaminants

Once the rapid systematic review protocol is established, ICF will work with the WACOR to complete rapid systematic reviews on the remaining CCL5 contaminants (approximately 245 contaminants). A task order will be sent to initiate this work and provide additional detail. EPA asks that the systematic reviews be completed in batches of 10-20 chemicals.

Task 4C. Execute Rapid Systematic Review Protocol on Six Year Review 4 Contaminants

Once the rapid systematic review protocol is established, ICF will work with the WACOR to complete rapid systematic reviews for all regulated contaminants considered under Six Year Review 4 (approximately 70 contaminants). A task order will be sent to initiate this work and provide additional detail and any modifications needed to the rapid systematic review protocol.

Travel: No travel is anticipated under this amendment.

Task	Milestones and Due Dates
Task 4: General Support of Systematic Review	
Task 4A: Develop Rapid Systematic Review Protocol	Rapid systematic review protocol developed and completed on 6 pilot contaminants
	Due: 6 weeks after initiation of Task 4A
	Rapid systematic review protocol completed for remaining CCL5 contaminants
Task 4B: Execute Rapid Systematic Review Protocol on CCL5 Contaminants	<b>Due</b> : TBD after completion of the rapid systematic review protocol; note that the December-January timeframe is in the draft schedule for CCL5 literature searches
Task 4C: Execute Rapid Systematic Review Protocol on Six Year Review 4 Contaminants	Rapid systematic review protocol completed for Six Year Review 4 contaminants
Six Teal Neview 4 Contaminants	<b>Due</b> : TBD after completion of the rapid systematic review protocol

### Appendix A: Rapid Systematic Review Protocol – Proposed Deliverable from ICF

# \*\*Note that HHRAB anticipates changes may need to be made to this deliverable as the rapid systematic review protocol is developed and piloted.

- 1. Check if the chemical is a pesticide and if EPA's Office of Pesticide Programs has an assessment
  - Search PCCL database using DTXSID number and look for if the compound has an entry with the source "fifra". This means that the compound is included on the list of registered pesticides and active pesticide ingredients and is a good indication that the compound will have an OPP assessment available.
  - If it is a pesticide, click this link: https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:0::NO:1::
  - o Type in the chemical name in the chemical name search bar and click go
  - Click on chemical name and click on Regulatory Actions tab
  - Identify any human health assessments in Document box:
    - Reregistration Eligibility Documents (REDs)
    - Interim Reregistration Eligibility Documents (iREDs)
    - tolerance Reassessment Eligibility Decision (tRED)
    - Health Effects Division Human Health Risk Assessments (HED HHRAs)
- 2. Check for existing assessments in PCCL database using DTXSID number (not chemical name)
  - If no assessment, use date unlimited search
  - If there is an assessment, the date used for beginning date of the literature search will be one year prior to the assessment publication date.
  - Assessments are defined as one of the following document types
    - ATSDR Toxicity Profile
    - CalEPA Public Health Goal
    - WHO Drinking Water Guideline
    - Health Canada Drinking Water Guideline
    - EPA Health Advisory or Health Effects Support Document (HESD)
    - EPA OP RED, iRED, tRED, or HED HHRAEPA IRIS Assessment
    - EPA PPRTV Assessment
- 3. Open SWIFT-Review
  - Click Tools, find chemical synonyms
  - o Type in chemical name or CAS number a list of synonyms will appear
    - Add this list of synonyms to the PECO Statement (see attachment A)
  - In the query that the computer generates, click the hyperlinked PMID text this will open a PubMed search window
  - Date limit the search (Publications dates custom range) based on the date of the last assessment
  - Click "sent to" send to file xml
    - Save file with dtxsid, name, date (day month year, 2 digits for day month and 4 for year)
      - For example: "dtxsid5036761 lithium 05072019.xml"
- 4. Filter Literature Search Results in SWIFT-Review
  - o Load reference file
  - Drawdown menu "Evidence Stream"
    - Record the number of animal studies and human studies in an Excel spreadsheet.
       Include a column for the DTXSID number, chemical name, # of animal studies and # of human studies
  - Select Animal in "Evidence Stream"
    - Select all studies in bottom half of screen (command a), right click, send to active viewer, new project, de-duplicate by title, name new project chemical name\_date
      - For example: "Lithium\_05072019"

- 5. Log in to SWIFT-Active Screener
  - Start new project
  - Make form to match the attached template (Attachment B)
    - Include if all of the following are true:
      - Mammalian model
      - Multiple treatment groups (> 1 dose group) and a control group
      - Subchronic exposure or chronic exposure (include if 28 days or more in rodent models), or include if study is targeting developmental or reproductive endpoints
      - Oral route of exposure (gavage, food or water)
      - Dose groups contain only the substance of concern, not mixtures
    - Exclude all other studies
    - Include studies if the abstract does not have enough information to know if the inclusion criteria are met (i.e., if you can't tell if the study qualifies, keep it in)
- 6. HERO (or the most efficient mechanism) for retrieving included studies
  - Work with EPA WACOR to determine how full text PDFs will be retrieved
- 7. Distiller, full text screen for relevancy
  - o Work with EPA WACOR to determine if a full text screening for inclusion/exclusion is necessary.
  - EPA WACOR will set up the Distiller project and populate the Distiller form to tag for relevance
- 8. HAWC for data extraction, study evaluation and risk of bias analyses
  - Work with EPA WACOR to determine what data to extract from each study, how to conduct the study evaluations and risk of bias analyses.

# **ATTTACHMENT A**

Replace the highlighted next with the appropriate info for each contaminant

# Table 1. PECO Statement for the PFOA

P	Human: Any population and lifestage (occupational or general population, including children and other sensitive populations).  Animal: Nonhuman mammalian animal species (whole organism) of any lifestage (including preconception, in utero, lactation, peripubertal, and adult stages).  In vitro/cell studies or in silico/modeling toxicity studies should be tagged as supplemental
E	Relevant forms: INSERT NAME HERE PFOA (CAS number 335-67-1). Other names: perfluorooctanoate, perfluorooctanoic acid, perfluoroctanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctanoic acid, Pentadecafluoro-1-octanoic acid, Pentadecafluoro-n-octanoic acid, Octanoic acid, pentadecafluoro-, Perfluorocaprylic acid, Pentadecafluorooctanoic acid, perfluoroheptanecarboxylic acid  Human: Any exposure to PFOA via oral routes. Other exposure routes, including inhalation, dermal or unknown/multiple routes, will be tracked during title and abstract screening and tagged as "potentially relevant supplemental information."  Animal: Any exposure to PFOA via oral routes. Other exposure routes, including inhalation, dermal, injection or unknown/multiple routes, will be tracked during title and abstract screening and tagged as "potentially relevant supplemental information." Studies involving exposures to mixtures will be included only if they include exposure to PFOA OR PFOS alone.
С	Human: A comparison or referent population exposed to lower levels (or no exposure/exposure below detection limits) of PFOA, or exposure to PFOA for shorter periods of time. Case reports and case series will be tracked as "potentially relevant supplemental information."  Animal: A concurrent control group exposed to vehicle-only treatment or untreated control.
o	All health outcomes (both cancer and noncancer).
PBPK Models	Studies describing physiologically-based pharmacokinetic (PBPK) models will be included

# Appendix B. Template form for SWIFT Active Reviewer

Table 1. Additional tags for studies not included during SWIFT active reviewer screening

Category	Evidence						
Mechanistic studies	Studies reporting measurements related to a health outcome that inform the biological or chemical events associated with phenotypic effects, in both mammalian and non-mammalian model systems, including in vitro, in vivo (by various routes of exposure), ex vivo, and in silico studies. When possible, mechanistic studies will be sub-tagged as pertinent to cancer, non-cancer, or unclear/unknown.						
Non-mammalian model systems	Studies in non-mammalian model systems, e.g., fish, birds, <i>C. elegans</i>						
ADME and toxicokinetic	Studies designed to capture information regarding absorption, distribution, metabolism, and excretion, including toxicokinetic studies. Such information may be helpful in updating or revising the parameters used in existing PBPK models.						
Acute/short-term duration exposures	Animal studies of less than 28 days						
Exposure characteristics	Exposure characteristic studies include data that are unrelated to toxicological endpoints, but which provide information on exposure sources or measurement properties of the environmental agent (e.g., demonstrate a biomarker of exposure).						
Susceptible populations	Studies that identify potentially susceptible subgroups; for example, studies that focus on a specific demographic, lifestage, or genotype.						
Mixture studies	Mixture studies that are not considered PECO-relevant because they do not contain an exposure or treatment group assessing only the chemical of interest.						
Non-oral routes of exposure	Studies not addressing routes of exposure that fall outside the PECO scope, include inhalation and dermal exposure routes						
Case studies or case series	Case reports and case series will be tracked as potentially relevant supplemental information.						
Records with no original data	Records that do not contain original data, such as other agency assessments, informative scientific literature reviews, editorials or commentaries.						
Conference abstracts	Records that do not contain sufficient documentation to support study evaluation and data extraction.						

Table 2. Additional tags for studies that are included during SWIFT active reviewer screening

Category	Evidence
Animal repeat dose – chronic/cancer	

Animal repeat dose – reproductive/developmental	
Animal repeat dose – multigenerational	
Animal repeat dose subchronic	
Human epi study	
PBPK model	

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Comments:									
Immediate Start Authorized									
Superfund	Acco	ounting and Approp	priations Data	1		Х	Non-Superfund		
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Work Assignment Manager Name Mary R	eiley				Branch/Mail Code:				
					Phone Number: 202-566-1123				
(Signature) (Date)					FAX Number:				
Project Officer Name Shirley Harri		nch/Mail Code:							
	Pho	Phone Number: 202-566-1107							
(Signature)	FAX	Number:							
Other Agency Official Name				Brai	nch/Mail Code:				
	Pho	Phone Number:							
(Signature) (Date)					FAX Number:				
Contracting Official Name Kathleen I		Branch/Mail Code:							
				Pho	Phone Number: 513-487-2853				
(Signature)		FAX Number:							

### PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-16-011 WORK ASSIGNMENT #3-17

**TITLE:** Support for National Water Program Research Coordination

### WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

Mary Reiley
Health and Ecological Criteria Division, 4304T
Office of Science and Technology, Office of Water
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Phone: 202-566-1123 Fax: 202-566-1139

### **ALTERNATE WACOR (ALT WACOR):**

Michael Elias Health and Ecological Criteria Division, 4304T Office of Science and Technology, Office of Water U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

Phone: 202-566-0120 Fax: 202-566-1139

**CONTRACT PWS**: 3.1.11, 3.4, 3.6, 3.7

LOE HOURS: 790

**PERIOD OF PERFORMANCE:** July 1, 2019 through June 30, 2020

### **BACKGROUND:**

The Office of Water (OW) Program Offices (Office of Science and Technology (OST), Office of Groundwater and Drinking Water (OGWDW), Office of Wetlands Oceans and Watersheds (OWOW), Office of Wastewater Management (OWM) and the Immediate Office (IO)) and Regions develop and maintain a National Water Program Research Strategy to: (1) outline programmatic objectives and research questions and detail the necessary scientific and technical investigations and products to answer them; and (2) advance collaboration with EPA and non-EPA investigators. The Strategy is a resource for National Water Program (NWP) staff and managers as they work with internal and external research organizations to leverage Water research needs. OW implements the Research Strategy through meetings, workshops, outreach, communications, annual reports, focused strategy and action plan development. The National Water Program (NWP) also maintains an Executive Committee for Research (Ex.Com) which is staffed by the NWP Research Points of Contact (POC). The Ex.Com and POC work together to identify the science, tools, and methods needed to advance programmatic goals and environmental outcomes and work with ORD, other researchers, and stakeholders to translate those needs into science questions and research portfolios. The POC is a liaison, information gatherer, and consensus builder between the Ex.Com., ORD, and other partners and stakeholders. The strategic planning, technical, outreach, and workshop support contemplated in this PWS is a continuation of work provided by the Office of Wastewater Management (OWM) Cadmus Group Contract (EP-C-12-023) during the contract option periods, WA #2-24, 3-24, 4-24, 5-24, and 6-24).

Objective 1: Provide program management and analysis, technical writing, meeting\*, workshop\*, and outreach support for the National Water Program Executive Committee for Research (Water-ECR made up of the OW DAA and OD's) and National Water Program Points of Contact (NWP-POCs made up of senior staff from OST, OGWDW, OWM, OWOW, IO, Regions, and the OW Associate Director for Science) related to research coordination between OW and other EPA Offices and current and potential non-EPA collaborators as well as Strategy maintenance and implementation.

\*Some meeting and workshop session costs are anticipated to reach the \$20K threshold for SRO approval.

Objective 2: Provide support to identify science needs and conduct and document strategic planning for the National Water Program Executive Committee for Research and NWP-POCs related to collaborative and coordinated research and science-based policy goals.

### **QUALITY ASSURANCE:**

The tasks in this work assignment do not require the use of primary or secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor does not need to supplement the Contract Level Quality Assurance Project Plan (QAPP) or to prepare a Project Specific Quality Assurance Project Plan (PQAPP).

### **PERFORMANCE WORK STATEMENT (PWS):**

### Task 1: Work Plan and Monthly Progress Reports

The contractor shall develop a work plan that describes how each task will be carried out. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. In addition, the workplan shall include the requirement that all electronic and information technology (EIT) and all EIT deliverables be Section 508 compliant in accordance with the policies referenced at <a href="http://www.epa.gov/accessibility/">http://www.epa.gov/accessibility/</a>. If a subcontractor(s) is proposed and subcontractors are outside the local metropolitan area, the contractor shall include information on plans to manage work and control costs.

In addition, the contractor shall prepare a statement indicating that this WA is a continuation of work under the OWM Cadmus Group Contract (EP-C-12-023, WA #2-24, 3-24, 4-24, 5-24 and 6-24) and will outline the transition process to ensure continuity in the work. In addition, the work plan shall specify that a Supplemental Project Specific Quality Assurance Project Plan (SQAPP) appending the Contract Level QAPP or a PQAPP is not required. This task also includes monthly progress and financial reports. The monthly progress report shall summarize activities conducted for the reporting period. Monthly financial reports must include a table with the invoice LOE and costs` broken out by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any laggings costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Deliverable: Work plan and monthly progress reports submitted in accordance with contract requirements.

### Task 2: Maintain National Water Research Strategy

The NWP Research Strategy will provide conceptual direction but the specific project needs must be adjusted from year to year to reflect changes in budgets, priorities, completed, and new work. The contractor shall maintain the National Water Research Strategy (in its Excel spreadsheet format) to reflect new areas and priorities for inquiry to support the National Water Program. Information and leads on new areas and priorities will be provided by EPA. As directed by the WACOR, the contractor shall update the Excel spreadsheet that serves as the science needs detail for the Strategy for the FY19-FY22 research planning cycle each year between June 1 and October 30 for annual adjustments with specific guidance and provided from the WACOR through technical direction. The contractor shall work with the WACOR to revise or prepare a narrative to provide context to the spreadsheet.

Deliverable: The spreadsheet will be maintained in Excel. The narrative will be maintained in Word.

### Task 3: Support to NWP-POCs and Water Executive Committee for Research

The contractor shall provide technical and public presentation and outreach writing, as well as meeting logistical and facilitation support for the research coordination activities and efforts of the NWP-POCs and NWP Executive Committee on Research. This support shall include the creation of: briefing materials (power point presentations, agendas, Fact Sheets, resource binders and contents, posters), outreach products, project and manuscript tracking coordination, spreadsheets, and schedules, and focused strategy and action plans, as well as meeting and workshop logistics, expert identification, invites, and facilitation.

3a. The contractor shall anticipate 1 meeting/briefing of the Ex.Com of 1 day duration in the Washington, D.C. area over the course of the period of performance that will likely require facilitation (basic familiarity with the NWP Research Strategy and ORD Strategic Research Plans is needed. Technical/scientific background is not necessary) and logistical assistance (note taking, advance materials, name placards, hotel block). The contractor can assume that EPA will provide the facilities (i.e., there is no need to plan for facilities or meal charges). EPA does not anticipate this meeting reaching the agency's \$20,000 threshold for meeting/conference spending outlined in Section I.

Deliverable: 1 OW-ORD Management Meeting: contractor facilitated, date TBD, 50 attendees, briefing materials, including but not limited to power point, spreadsheets, and fact sheets delivered in appropriate electronic format as identified by the WACOR.

3b. The contractor shall anticipate 1 expert technical workshop of 2.5 days in duration in the Washington, D.C. area, for 50 people, in Sept-Oct 2019 timeframe. The contractor shall provide logistical (including venue, room block, name badges, advance materials, note taking, etc.), facilitation (including materials/tools), assist identifying expert participants, manage invitations, pre-meeting preparations (agendas, advanced conference calls/webinars, etc.) and post meeting materials (proceedings document, compilation of presentations, etc.)

Deliverable: 1 Experts Technical Workshop: facilitated 2.5 days workshop for 50 invited attendees (contractor provide travel and accommodation for 4 international and 12 from across the US), pre and post meeting materials, venue, logistics, experts identification/invitation.

3c. The contractor shall anticipate preparing a Strategy pamphlet, or poster for use with current and potential collaborators that shall be web-ready (PDF and 508 compliant) and delivered in

Word (or the appropriate software for the content and purpose) and PDF. Presentation posters shall have a maximum finished size of 3' x 4'and printed in full color on quality stock.

Deliverable: Anticipate delivery of: 1 poster; 1 pamphlet.

3d. The contractor shall maintain a manuscript review tracking spreadsheet and work with the WACOR and lead staff to coordinate reviews and comments on manuscripts for which official review has been requested across the National Water Program and through OW-IO. The contractor shall anticipate tracking approximately 75 manuscripts distributed over the course of a year. Access to the Share-Point Site containing the tracking spreadsheet will be made available through the WACOR. The WACOR and contractor shall design an SOP for tracking/review process.

Deliverable: Real-time manuscript entry and updates to the tracking spreadsheet. Minimum of weekly updates on manuscript status during weekly call with WACOR. More frequent WACOR-contractor conversations/email should a manuscript review be particularly challenging, delayed, or have other complicating factors.

### **SCHEDULE OF DELIVERABLES:**

Task	Deliverable	Due to EPA	No of Copies/Medium		
1	Work Plan and Monthly Progress Reports	Per Contract Requirements	Per Contract Requirements		
2	Excel spreadsheet for annual adjustments	Between June 1 and October 30 (planning cycle)	Electronic Excel		
2	Narrative context to spreadsheet	Updated concurrently with spreadsheets	Electronic Word		
3a	OW-ORD Management Meeting briefing materials and facilitation	Provided per Technical Direction	Approx. 40/ Electronic Format		
3b	Experts Technical Workshop	Anticipate Sept-Oct 2019	Approx. 50/ Electronic Format Word, Excell, PDF, potentially 508 compliant		
3c	Poster and/or Pamphlet	Provided per Technical Direction	Poster: 1 in hardcopy as above and Electronic PDF and 508; Pamphlet: 1-page double sided Electronic PDF, 508, and Word		
3d	Manuscript review tracking spreadsheet and review/comment coordination	Real-time tracking	Excel Spreadsheet in SharePoint		

### **CONFERENCE/MEETING GUIDELINES AND LIMITATIONS:**

The contractor shall immediately notify the EPA Contracting Officer, CL COR and WACOR of any anticipated event involving support for a meeting, conference, workshop, symposium, retreat, seminar or training that may potentially incur \$20,000 or more in cost during performance. Conference

expenses are all direct and indirect costs paid by the government and include any associated authorized travel and per diem expenses, room charges for official business, audiovisual use, light refreshments, registration fees, ground transportation and other expenses as defined by the Federal Travel Regulations. All outlays for conference preparation should be included, but the Federal employee time for conference preparation should not be included. After notifying WACOR of the potential to reach this threshold, the contractor shall not proceed with the task(s) until authorized to do so by the Contracting Officer.

#### TRAVEL:

Travel is authorized for quarterly meetings with the WACOR (if determined to be needed by the WACOR via technical direction) and facilitating workshops and meetings. Quarterly Contractor-WACOR meetings (typically 1.5 hours) and up to two workshops and meetings (typically 1-2 days) would be held at EPA Headquarters in Washington, D.C. All travel shall be pre-approved by the WACOR and the Contract-Level COR prior to travel in accordance with EPA and FAR requirements.

#### **SPECIAL REPORTING REQUIREMENTS:**

The contractor shall hold weekly 30-60 minutes conference calls for planning purposes with the WACOR to provide updates on project status, next steps, and resolve challenges. More frequent communications via email/phone are necessary if there are delays or other impediments to timely completion. The contractor shall report the number of hours and funds expended monthly in each monthly report tracking the workshop separately from other activities.

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Work Assig	nment M	anager Name	Mary Reil	ey				Branch/Mail Code:				
						Phone Number: 202-566-1123						
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### PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-16-011 WORK ASSIGNMENT #3-17 Amd 1

TITLE: Support for National Water Program Research Coordination

### WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

Mary Reiley
Health and Ecological Criteria Division, 4304T
Office of Science and Technology, Office of Water
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Phone: 202-566-1123 Fax: 202-566-1139

# **ALTERNATE WACOR (ALT WACOR):**

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**CONTRACT PWS**: 3.1.11, 3.4, 3.6, 3.7

**PERIOD OF PERFORMANCE:** Date of Issuance through June 30, 2020

**PURPOSE OF AMENDMENT:** The purpose of this amendment is to provide travel support for one ICF contractor personnel to travel to and from the Washington, DC area to participate in the Frequency and Duration Workshop being held September 11 and 12, 2019. Travel details will be provided by the WACOR. According to the approved workplan, contractor's travel to, from, or outside of the Washington, DC area must be approved by the WACOR and the EPA Contract-Level COR prior to trip.

In addition to travel support, local travel by the contractor is anticipated for this work assignment. Authorization for local travel will be provided by the WACOR through technical direction, as deemed necessary by the WACOR. There is enough Travel funding provided in the work assignment to cover these expenses. No revised cost estimate is needed for this amendment.